	INTERD GENERA DIGENTAN GATTAN	Page 1		
1	UNITED STATES DISTRICT COURT			
2	SOUTHERN DISTRICT OF WEST VIRGINIA			
3	AT CHARLESTON			
4 5 6	IN RE ETHICON, INC., PELVIC: REPAIR SYSTEM PRODUCTS: MASTER FILE LIABILITY LITIGATION: No. 2:12-MD-02327 :			
7	THIS DOCUMENT RELATES TO : MDL 2327			
8 9	WAVE 4 CASES : GYNEMESH PS and PROLIFT : JOSEPH R. GOODWIN : US DISTRICT JUDGE			
10				
11				
12	March 12, 2017			
13				
14	CONFIDENTIAL			
15	Deposition of HARVEY A. WINKLER, M.D.,			
16	held at Butler Snow LLP, 1700 Broadway,			
17	New York, commencing at 4:10 p.m., on the			
18	above date, before Marie Foley, a Registered			
19	Merit Reporter, Certified Realtime Reporter			
20	and Notary Public.			
21				
22	GOLKOW TECHNOLOGIES, INC.			
23	877.370.3377 ph 917.591.5672 fax			
24	Deps@golkow.com			

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1	APPEARANCES:		1		
2			2	EXHIBITS	
3	ZONIES LAW LLC		3		
4	BY: GREG BENTLEY, ESQUIRE		4	NO. DESCRIPTION PAGE	
5	CHELSEA THOMPSON, ESQUIRE		5	Winkler 1 Amended Notice to Take	3
6	1900 Wazee Street, Suite 203		6	Deposition of Harvey	
7	Denver, Colorado 80202		7	Winkler, M.D., dated March	
8	720.464.5300		8	9, 2017	
9	Representing the Plaintiff		9	Winkler 2 Expert Report of Harvey 8	
10	J		10	Winkler, M.D. Regarding	
11			11	Gynemesh PS and Prolift,	
12			12	dated February 5, 2017	
13	BUTLER SNOW LLP		13	Winkler 3 Curriculum Vitae of Harvey 8	: I
14	BY: PAUL S. ROSENBLATT, ESQUIRE		14	Winkler, M.D.	
15	1020 Highland Colony Parkway		15	Winkler 4 Supplemental General 9	
16	Suite 1400		16	Reliance List in Addition	
17			17	to Materials Referenced in	
18	Ridgeland, Missouri 39157 601.948.5711				
			18	Report MDL Wave 4	,
19	paul.rosenblatt@butlersnow.com		19	,	9
20	Representing the Defendant		20	Winkler, M.D., dated	
21			21	January 17, 2017	
22			22		
23			23		
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3 4 5 6 7 8	PAGE APPEARANCES		2 3 4 5 6 7 8	NO. DESCRIPTION PAGE Winkler 6 North Shore LIJ 47 Institutional Review Board Proposal Cover Sheet, Bates No.	
3 4 5 6 7 8 9	PAGE APPEARANCES		2 3 4 5 6 7 8 9	NO. DESCRIPTION PAGE Winkler 6 North Shore LIJ 47 Institutional Review Board Proposal Cover Sheet, Bates No. ETH.MESH.00411090	
3 4 5 6 7 8 9	PAGE APPEARANCES		2 3 4 5 6 7 8 9 10	NO. DESCRIPTION PAGE Winkler 6 North Shore LIJ 47 Institutional Review Board Proposal Cover Sheet, Bates No. ETH.MESH.00411090 Winkler 7 Monitoring Reports, Bates 51	
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2	EXHIBITS	2	4:10 p.m.
3		3	New York, New York
4	NO. DESCRIPTION PAGE	4	
5	Winkler 15 The American College of 171	5	HARVEY A. WINKLER, M.D., the Witness herein,
6	Obstetrics and	6	having been first duly sworn by a
7	Gynecologists Committee	7	Notary Public in and of the State of
8	· · · · · · · · · · · · · · · · · · ·	8	•
	Opinion, dated December 2011		New York, was examined and testified as
9	Winkler 16 Dandolu article 185	9	follows:
10	Winkler 21 Gynemesh PS Early Clinical 228	10	/Fightheth Mindley 4 Annual ded
11	Experience	11	(Exhibit Winkler 1, Amended
12	Winkler 22 Color copy photograph 230	12	Notice to Take Deposition of Harvey
13	Winkler 17 Diwadkar article 239	13	Winkler, M.D., dated March 9, 2017,
14	Winkler 18 Maher article 241	14	was marked for identification, as of
15	Winkler 19 Sokol article 243	15	this date.)
16		16	(Exhibit Winkler 2, Expert
17		17	Report of Harvey Winkler, M.D.
18		18	Regarding Gynemesh PS and Prolift,
19		19	dated February 5, 2017, was marked for
20		20	identification, as of this date.)
21		21	(Exhibit Winkler 3, Curriculum
22		22	Vitae of Harvey Winkler, M.D., was
23		23	marked for identification, as of this
24		24	date.)
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Page 7 DEPOSITION SUPPORT INDEX DIRECTION TO WITNESS NOT TO ANSWER Page Linenone REQUEST FOR PRODUCTION OF DOCUMENTS Page Line 10 23 15 3 STIPULATIONS Page Linenone QUESTIONS MARKED Page Linenone	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	(Exhibit Winkler 4, Supplemental General Reliance List in Addition to Materials Referenced in Report MDL Wave 4, was marked for identification, as of this date.) (Exhibit Winkler 5, Invoice No. 1010 of Harvey Winkler, M.D., dated January 17, 2017, was marked for identification, as of this date.) EXAMINATION BY MR. BENTLEY: Q. Good afternoon, Doctor Winkler. We just finished your deposition regarding your TVT and TVT-Exact report. We're going to start now with your deposition covering your report on Prolift and Gynemesh PS. Do you understand that? A. Yes, I do. Q. For the record, we're marking as Exhibit 1 the Notice of Deposition, which
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	DEPOSITION SUPPORT INDEX DIRECTION TO WITNESS NOT TO ANSWER Page Linenone REQUEST FOR PRODUCTION OF DOCUMENTS Page Line 10 23 15 3 STIPULATIONS Page Linenone	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	(Exhibit Winkler 4, Supplemental General Reliance List in Addition to Materials Referenced in Report MDL Wave 4, was marked for identification, as of this date.) (Exhibit Winkler 5, Invoice No. 1010 of Harvey Winkler, M.D., dated January 17, 2017, was marked for identification, as of this date.) EXAMINATION BY MR. BENTLEY: Q. Good afternoon, Doctor Winkler. We just finished your deposition regarding your TVT and TVT-Exact report. We're going to start now with your deposition covering your report on Prolift and Gynemesh PS. Do you understand that? A. Yes, I do. Q. For the record, we're marking as

Page 10 Page 12 1 Exhibit 2 is your report 1 mesh. So those are going to be the same. 2 regarding Prolift and Gynemesh PS. 2 Then I have basis regarding specifically 3 Exhibit 3 will be a copy of your 3 mesh that is used in the Gynemesh, which 4 CV, which was also previously marked in 4 is, as you know, a lighter-weight mesh 5 the previous deposition. 5 than is used in the TVT mesh. So, there's 6 6 Exhibit 4 will be your reliance general mesh and then there's specific to each product. 7 list that was also marked in the previous 7 8 8 deposition. Q. Is that delineated in some way 9 9 Then I'm going to mark right now in your material list? which is Exhibit 5, which is your invoice I think in reviewing it all, I 10 10 for your time billed to date for the POP would take it all in context that it's 11 11 report; is that correct? together, but in writing the report, I 12 12 13 tried to separate it out. Α. Yes. 13 Q. And I'm talking specifically 14 Q. Does this invoice reflect all of 14 about the reliance list, it's all combined 15 the time that you spent researching and 15 writing your Prolift report? 16 16 together. There's probably some more. I A. I understand. 17 17 18 have not added that up together as that's 18 There's no way to split up your Q. only current 'til about 12/24/2016. I reliance list for your prolapse report 19 19 versus your incontinence report, right? 20 sent the bill out about 1/17. So probably 20 A. I think it was -- both of -- all 21 current 'til about 1/17. There's probably 21 22 more that happened after that. of it gave my gestalt for what's going on 22 23 MR. BENTLEY: We'd request a 23 and my opinions. 24 copy of the later invoice if one is 24 Q. There's a number of internal Page 11 Page 13 submitted. 1 documents with Bates of ETH.MESH and 1 2 BY MR. BENTLEY: 2 H.MESH, for example. 3 3 Q. The reliance list that you Did you review all of those? 4 attached or that you served with your 4 A. Yep. I may not have read 5 Prolift report, that's the same reliance 5 everything word for word, or else we'd 6 list that you submitted with your TVT 6 probably be here for years, but I did 7 report; is that correct? 7 review everything. 8 Q. How did you decide which 8 Α. That's correct. 9 9 internal documents to review? Did you rely upon the TVT 10 evidence in reaching your conclusions in 10 A. I would read the first sentence 11 your Prolift report in addition to the 11 or two and see what it's pertaining to and other literature? I would decide if I should review the 12 12 A. I tried to separate out a lot of 13 13 entire document or if I should just skim the TVT literature from the prolapse 14 14 15 literature. There may be some in my 15 There's approximately seven 16 report that is overlying, but in the 16 pages of internal documents that it says reports I tried to separate it out. I may 17 17 you relied upon. not have done that a hundred percent. Is that consistent with your 18 18 recollection of your review of Ethicon 19 Q. Looking at what's marked as 19 Exhibit 4, which is your reliance list, 20 20 documents? how would we go back and look at which 21 21 Α. 22 materials are the basis for your Prolift 22 And your invoice indicates that Q. report as opposed to your TVT report? you spent 2.0 hours reviewing Ethicon 23 23 24 Well, I have basis regarding 24 papers.

Page 14 Page 16 of plaintiff expert reports; is that 1 Is that the time you would have 1 2 spent reviewing internal documents? 2 correct? 3 3 That would be one of them. So, A. Yes, I did. 4 that may have been not in a binder that 4 It looks like you reviewed a Q. 5 was sent to me. I received binders and 5 number of TVT and TVT-O reports, but only 6 papers and papers of stuff, and I tried to 6 two Prolift reports were plaintiffs. 7 review some in more depth and some in less 7 Is there any reason why it seems 8 8 you reviewed many more TVT reports as depth. 9 9 opposed to prolapse-related reports? Do I have a systematic way that I can do checkboxes for you? No, I don't. 10 10 A. That was what was sent to me, so Your reliance list indicates that's what I reviewed. 11 11 that you reviewed a number of company 12 12 O. When you were reviewing these 13 deposition transcripts; is that correct? materials, did you specifically request 13 any further documents or reports after you 14 A. Yes, I did. 14 15 Q. Did you review the entirety of 15 started reviewing? those transcripts or just portions? 16 16 So, there were sometimes I would Some of it were just portions. discuss with them and say -- and saying, 17 17 18 Some of them I may have written in a 18 This is what I've read. Do you have the full deposition? And the full deposition 19 little more -- I may have read a little 19 more in depth. I don't recall which ones 20 20 would be sent to me. 21 were more in depth than the others. 21 There were -- there was articles 22 Were you provided the entire 22 and literature that I actually sent over 23 transcript, or were you provided excerpts 23 to J&J as part of my literature searches 24 of the company depositions? 24 that I found that were not included in Page 15 Page 17 Some of it I was given the 1 documents that I thought may and should be 1 included in some of their documents in the 2 entire. Some of it was just excerpts. 2 MR. BENTLEY: Plaintiffs would 3 3 future. So, there was a back-and-forth 4 request that they be provided 4 for the last several months regarding 5 5 supplemental material list indicating information. 6 what was actually provided and relied 6 Q. And do you know any plaintiff 7 upon by Dr. Winkler. 7 experts outside of this litigation? 8 MR. BENTLEY: Let me rephrase 8 BY MR. BENTLEY: 9 9 Then there's a number of it. 10 depositions of the plaintiff experts. 10 Prior to your engagement in this 11 Similarly, did you review the 11 litigation, did you know of any of entire transcript for the depositions of plaintiff's expert witnesses? 12 12 the plaintiff's experts? So, I had heard, I did not know 13 13 A. Some of them I had. Some of specifically, and I did not see it 14 14 specifically, who those plaintiff experts 15 them gave multiple depositions, so I don't 15 16 recall which ones I read the entirety of 16 were, but there was hearsay that certain and which ones I read the -- sort of just people that we knew were expert witnesses, 17 17 skimmed them. 18 18 yes. Were you provided the entire 19 19 So you knew some of these other 20 transcripts of those depositions or just physicians in your career, in your 20 21 excerpts? 21 practice? 22 22 To my best of my recollection, I Yeah, I know some of them Α. Α.

5 (Pages 14 to 17)

23

24

personally.

Q.

Which ones do you know

was provided the entire transcripts.

And then you reviewed a number

23

24

Page 18 Page 20 1 personally? 1 deposition testimony from this morning and 2 2 early afternoon from the TVT so we don't Let me get to the list and I'll 3 3 have to retread a lot of the background tell vou. 4 4 and general stuff. Q. It's, I believe, on the last 5 page of Exhibit 4. 5 A. Sure. 6 Okay. I know Jerry Blavis. I 6 But you testified earlier that your opinions today -- well, your opinions 7 Neerak Kohli. I know Don Ostergard, 7 8 although I'm not sure if he would remember 8 as disclosed in these reports are based 9 9 upon your review of the literature in who I am. I've met Bruce Rosenzweig maybe addition to your clinical practice; is 10 once or twice way early in my career when 10 I was in Chicago. Dionysios Veronikis that correct? 11 11 I've met. I don't have his e-mail or 12 12 A. That's correct. 13 anything like that. Let's see. Okay. And presumably, all these 13 experts also reached opinions based off of 14 So, that's it from this list. 14 their review of the literature and their 15 Based off that testimony, the 15 Q. 16 people that you've listed that you are 16 private practice. familiar with or you know, do you have any 17 17 Would you agree with that? 18 reason to doubt their expertise or 18 A. Yeah, I would agree that they -abilities in their fields? 19 19 that's their opinions. 20 A. I think they're all experts. I 20 And for whatever reason, you all 21 think some of them are stronger experts in 21 have come to differing conclusions based 22 certain things than other things. off of both of your experience and their 22 23 And they looked at the same 23 experience and based off of their review 24 information you did and just came to 24 of the literature and your review of the Page 19 Page 21 different conclusions? 1 literature? You all were looking at most 1 of the same information; you've reached 2 MR. ROSENBLATT: Object to form. 2 3 3 MR. BENTLEY: Let me rephrase different conclusions; is that correct? 4 4 A. We have reached different it. 5 5 BY MR. BENTLEY: conclusions, that's correct. 6 Q. You don't have any criticisms of 6 Okay. So really where I'm going 7 their qualifications, do you? 7 is do you have any criticisms specifically 8 of their methodology for reviewing the 8 Α. No, I do not. 9 9 literature and the data to reach their And you looked at their materials and the materials they looked 10 conclusions specific to their methodology 10 11 at, right? 11 since you reviewed their reports? A. I'm not familiar -- I can't 12 A. That is correct. 12 13 And they, based off of their 13 comment on their methodology. I wasn't review of that information that you looked there doing the searches with them. I 14 14 wasn't there reading the articles with 15 at also, they came to conclusions that are 15 16 just different from your conclusions here, 16 them. So I can't comment on their methodology. 17 right? 17 I think most of their I can accept their conclusions, 18 18 but I don't know how they did their 19 conclusions may have been based on 19 searches personally. personal experience than some of the 20 20 O. We had previously discussed literature that I found. 21 21 what's been marked as Exhibit 3, which is 22 Q. Well, you've testified -- well, 22 and let's make it clear. your CV. I just want to go to the section 23 23 24 We're incorporating the 24 on studies you've been involved in with

Page 22 Page 24 1 grants, which I believe starts on -- page 1 treatments did you learn to treat women 2 8 has your research interests. 2 that suffered from pelvic organ prolapse? 3 3 A. So, in residency, I was taught Α. Yes. 4 4 mostly native tissue repairs, vaginal Q. We discussed a little bit you're 5 interested in developing a model to assess 5 hysterectomy, anterior and posterior 6 various types of meshes; is that correct? 6 colporrhaphy, as well as sacrospinous 7 7 suspension and some uterosacral Α. Yes. 8 8 suspension, and I wouldn't qualify that as And those meshes, we discussed a 9 9 high uterosacrals back then. My residency little bit in the TVT deposition, but really the meshes that you're looking at was very focused on abdominal-type stuff, 10 10 in developing the model, those are more and vaginal prolapse repair actually was 11 11 for pelvic floor reconstruction as opposed not numbers that we got in high numbers. 12 12 to the treatment of incontinence; is that And that was one of the reasons why I 13 13 wanted to go ahead and do a fellowship and 14 correct? 14 gain additional knowledge and bring that 15 A. Not necessarily. 15 knowledge back to the New York area. 16 16 Okay. O. It's really early stages. So we O. And so, your residency was 17 17 18 have to try to see where it goes. 18 focused on the abdominal approach for Q. Okay. On the next page there's 19 19 surgery, so were you performing the abdominal sacrocolpopexy? 20 your contracts, grants and sponsor 20 No, didn't do it. I said more 21 research, and you have a number of studies 21 22 22 abdominal-type of surgery it was focused here. 23 You've done studies evaluating 23 on as opposed to prolapse surgery. If we 24 mesh-based repairs for prolapse, right? 24 were doing prolapse surgery in my Page 23 Page 25 A. Yes, I have. 1 residency, it was vaginal hysterectomy, 1 uterosacral suspension, anterior and 2 And the earliest study you have 2 Q. 3 3 on here is an investigation titled posterior repair. 4 "Non-funded safety and efficacy of 4 When did you start using mesh to 5 5 sacrocolpopexy with synthetic mesh." repair prolapse? 6 Α. Yes. 6 So, abdominally, I started in my 7 What kind of mesh would you have 7 fellowship. We didn't use mesh there. We Q. 8 used Gore-Tex. And then probably when I 8 been investigating in that study? 9 A. It was likely that it was 9 finished fellowship, we started using the 10 10 regular Prolene mesh that we had discussed Gynemesh PS. 11 O. Let's back up a little bit. 11 earlier this morning, and then -- and we This deposition is about were cutting pieces of the Prolene mesh. 12 12 13 products that are polypropylene-based that 13 And then when the Gynemesh PS came out, or are used to treat the indication of the Prolene Soft came out, we transitioned 14 14 15 15 over to the soft version from the original prolapse. 16 Is that fair? 16 Prolene mesh version. O. I think you just testified that 17 17 A. Yes. And during your residency, did you used Gore-Tex first? 18 18 you learn about the -- did you learn about 19 19 A. Gore-Tex, yes. That was in women that suffered from prolapse and how 20 20 fellowship. 21 to treat that? 21 And I might have heard you Q. 22 22 A. Yes. wrong. 23 And during your residency, how 23 I think you said the Gore-Tex 24 were you taught, or what surgical 24 was not a mesh?

	Page 26		Page 28
1	A. It wasn't it was a Gore-Tex	1	Q. Do you know that there were more
2	sheathe. It was a piece of sheathe. You	2	than one version of Prolene mesh that
3	can call it a mesh, but it wasn't the	3	Ethicon made and manufactured?
4	meshes that we're talking about today.	4	A. I was familiar with there were
5	Let's put it that way.	5	more than one version. I just don't
6	Q. It wasn't a polypropylene mesh?	6	remember which version. I think we tried
7	A. Yes.	7	to find a version that had the biggest
8	Q. So you started with Gore-Tex	8	pores back then.
9	mesh, and what were the results with using	9	But now we're really going back
10	Gore-Tex to treat prolapse?	10	15, 16 years.
11	A. So, Gore-Tex encapsulates, it's	11	Q. You said that Gore-Tex mesh
12	microporous, and there was a higher	12	didn't work in part because it was
13	erosion higher exposure rate with the	13	encapsulated?
14	Gore-Tex meshes. We didn't do a lot of	14	A. Correct.
15	sacrocolpopexies in fellowship. I	15	Q. And what exactly do you mean by
16	probably got the majority of my experience	16	"encapsulated"?
17	with sacrocolpopexy when I finished	17	A. So, tissue could not grow into
18	fellowship, actually, when I went to	18	the mesh. Tissue can only grow around the
19	Maimonides and when I came over to to	19	mesh. And therefore, there was sort of a
20	North Shore. I had extensive experience	20	pocket that developed and went around the
21	in abdominally-based surgery from my	21	Gore-Tex meshes.
22	residency, but I did not have a large	22	Q. Is that kind of like scar
23	volume of numbers of sacrocolpopexies	23	plating?
24	until then.	24	A. I wouldn't say it's scar
21	and aren.	۷ -	A. I Wouldn't Suy it's Scal
	Page 27		Page 29
1	Q. In approximately what time frame	1	plating. I would say there's tissue
2	were you using the Gore-Tex to treat	2	growing over it, because one of the things
3	prolapse?	3	that happened with the Gore-Tex is that
4	A. That was '96 to '98.	4	tissue didn't it didn't grow into it.
5	Q. And then from '98 in 1998 you	5	So it was something that extruded fairly
6	began using Prolene?	6	easily.
7	A. Prolene.	7	Q. When it encapsulated the mesh,
8	Q. Do you know what construction of	8	did it make the tissue harder and less
9	Prolene you were using in 1998 to treat	9	flexible?
10	prolapse?	10	A. I don't recall.
11	A. It was the Prolene mesh that	11	Q. Then when did you start using
12	Ethicon made.	12	Prolene Soft to treat prolapse?
13	Q. Right. And you may not know,	13	A. So, probably when it came out.
14	there's several iterations of Prolene mesh	14	I don't remember exactly. My
15	and sutures under the same name.	15	understanding was Prolene Soft came out in
	and surfice under the salle halle.	LIJ	<u> </u>
16		16	2002 3
16 17	In 1998 when you were using	16 17	2002, '3.
17	In 1998 when you were using Prolene mesh to repair prolapse, do you	17	Do you know?
17 18	In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction	17 18	Do you know? Q. Did you consult on the design of
17 18 19	In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction of Prolene mesh that was?	17 18 19	Do you know? Q. Did you consult on the design of Prolene Soft?
17 18 19 20	In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction of Prolene mesh that was? A. So, it wasn't the Prolene PS.	17 18 19 20	Do you know? Q. Did you consult on the design of Prolene Soft? A. No, I did not.
17 18 19 20 21	In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction of Prolene mesh that was? A. So, it wasn't the Prolene PS. Q. Okay.	17 18 19 20 21	Do you know? Q. Did you consult on the design of Prolene Soft? A. No, I did not. Q. Do you recall if you did any
17 18 19 20 21 22	In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction of Prolene mesh that was? A. So, it wasn't the Prolene PS. Q. Okay. A. What they called it from before,	17 18 19 20 21 22	Do you know? Q. Did you consult on the design of Prolene Soft? A. No, I did not. Q. Do you recall if you did any studies on Prolene Soft to treat prolapse?
17 18 19 20 21	In 1998 when you were using Prolene mesh to repair prolapse, do you know one way or another which construction of Prolene mesh that was? A. So, it wasn't the Prolene PS. Q. Okay.	17 18 19 20 21	Do you know? Q. Did you consult on the design of Prolene Soft? A. No, I did not. Q. Do you recall if you did any

2002, then in the study that we did, there probably were patients who got Prolene Soft, but I don't remember the exact date things came out.

- Q. So you may have included patients that got Prolene Soft in a study, but you don't think you were working as a study investigator on an Ethicon-sponsored study; is that correct?
- A. This was not an Ethicon-sponsored study, the one that we did in the early 2000s.

I'm trying to see if we did anything that was Ethicon sponsored.

- Q. I just don't see any Ethicon activities on your CV, but based on your earlier testimony, it seems like you did some consulting for Ethicon, right?
- A. So, what I did for Ethicon was preceptorships, and I think I went to one or two consulting meetings that they had beforehand that I saw from paperwork that I didn't even remember.

I did not -- so, what was

Page 30

1 documents that refreshed your memory that
2 in 2004 you worked as a KOL for Ethicon;

- is that correct?
 A. I went to some meeting for them
 - that they sponsored as a, I guess, KOL. Q. Which is a key opinion leader, right?
 - A. Yes.
 - Q. And what did those documents that you were shown show you about your opinions in 2004 regarding mesh?
 - A. Back then, I was also concerned about an exposure rate, that exposure can happen with the meshes. It was something that I knew and it was a concern of mine.
 - Q. And were you concerned with any of the design properties of the mesh as they related to the exposures?
 - A. So, one of the things that I had said and that I guess they had documented, that I was worried about the tanged edges causing an exposure. However, I was proven incorrect because most of the exposures are not happening at the edges,

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happening was when the Gynemesh PS came out, I also implanted some of that Gynemesh PS transvaginally, and I guess they wanted to get my opinions on the transvaginal placement of the Gynemesh PS.

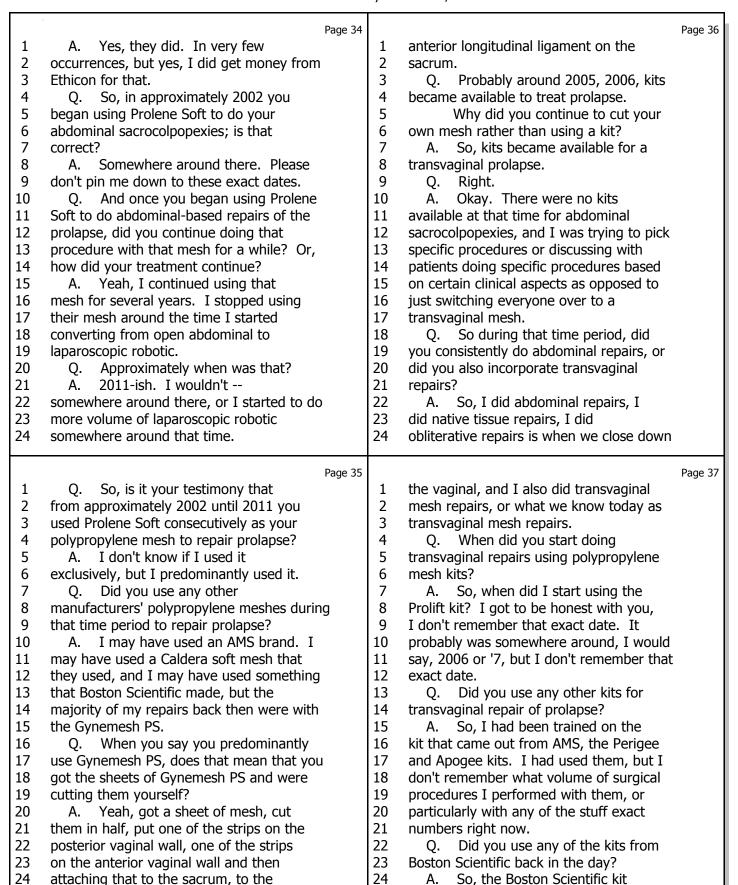
My partner, Dr. Lind, did more work with Gynecare, and so I don't know, can't remember what was going on back then.

- Q. In your work in this litigation, Ethicon didn't provide you any information to refresh your memory about consulting work that you did with them or studies that you participated on?
- A. They did. They showed me a piece of paper from 2004 where I participated in I guess one of these key opinion leader-type groups on transvaginal mesh, getting my ideas, but I did not participate in the design of the Prolift mesh.
- Q. Based on the documents you reviewed in preparation for this report and in this litigation, you were shown

they're happening at the incision lines in the middle of the mesh.

- Q. And those documents you may have actually referred to the edges as rough edges rather than tanged edges; is that correct?
- A. I don't remember how I referred to them, and how I referred to them may not be the way that the person wrote it down.
- Q. So other than some documents indicating that you were a KOL in 2004 and giving opinions regarding mesh and potential exposure, were you shown anything else to refresh your memory about your work as a consultant or participating in studies for Ethicon?
- A. So, I was shown that, and I know that I was not shown monies that I received, but I know that I was a preceptor.
- Q. And did Ethicon pay for you to travel and speak on behalf of the company or their products, that you remember?

Page 33



			,	1
	Page 38			Page 40
1 came out after the after the Apo	gee,	1	situation.	
2 Perigee, and Ethicon transvaginal r	nesh	2	Q. And were all three of these	
3 kits. And the Boston Scientific mes	sh kit	3	different kits available at your hospital	
4 was a little different than the Prolif	t	4	at any given time, or is there just one	
5 kit where you were able to get apid		5	brand purchased?	
6 support on a more systematic basis		6	A. I think they were available. I	
7 you were with the anterior Prolift.	o chan	7	can't recall exactly, but I think both of	
8 Q. Was that important for you	12	8	them either were available.	
9 A. Yeah. So, if patients had	4 •	9	MR. ROSENBLATT: I just wanted	
10 anterior and apical prolapse and th	ACV.	10	to object to form to they weren't all	
	•	11	available at the same time. So that's	
didn't have anything posteriorly, it beneficial.	was	12		
			my objection.	
13 Q. What aspect of the Boston		13	BY MR. BENTLEY:	
14 Scientific kit enabled you to get at		14	Q. So, when you started using	
15 apical support?		15	transvaginal kits around 2006 after the	
16 A. So, there was an arm that		16	introduction of Prolift, what percent of	
17 to sacrospinous ligament, and you	would	17	the woman that you treated for prolapse	
18 attach the arm of the mesh to the		18	would you use the abdominal approach	
19 sacrospinous ligament, or bring it t	_	19	versus the transvaginal kit?	
20 the sacrospinous ligament, to be m	nore	20	A. So, the abdominal approach we	
21 accurate.		21	were doing much more. So, I would say	
22 Q. So, when the Boston Scien		22	abdominally we probably used on prolapse	
23 kit became available, did you switc	h over	23	around 30 to 40 percent of the patients	
24 to that kit for your main kit to do		24	and kits were probably 10, maybe 15	- 1
				-
	Page 39			Page 41
1 transvaginal repairs?		1	percent.	
2 A. I don't remember the exact		2	Q. And what would be the other	
3 transition, but I may have transitio	ned	3	percent?	
4 over. The yeah.		4	A. Native tissue vaginal.	
5 Q. Because in the last deposit		5	Q. By those estimates,	
6 we discussed that you would use a	Boston	6	approximately half of the cases	
7 Scientific sling if you were doing a		7	approximately half of the women you were	
8 Boston Scientific-based mesh repai	r for	8	treating for prolapse once Prolift was	
9 prolapse, right?		9	available, once Gynemesh PS was available	,
10 A. That's what I do today. I'r	n a	10	approximately half of the women you were	
11 little more cognizant of it because	of all	11	treating you were using a native tissue	
12 this litigation as opposed to mixing		12	vaginal-based repair?	
13 things up.		13	A. Very grossly. Maybe 45. Very,	
14 Q. So, when you began using	the	14	very grossly, gross numbers here.	
15 Prolift kit around 2006 or 2007 die	l vou	4 -	Q. Did you have good results using	
LIJ PIUNIL KIL ATUUNU ZUUD UF ZUU/, QK	4 y O U	15	Q. Did you have good results using	
15 Prolift kit around 2006 or 2007, did 16 also use the AMS kit?	, you	15 16	, ,	
16 also use the AMS kit?		16	native tissue repair?	
16 also use the AMS kit? 17 A. No, I think I was mostly us		16 17	native tissue repair? A. Yes, I did. Yes, I still do.	
16 also use the AMS kit?17 A. No, I think I was mostly us18 the Prolift kit.	iing	16 17 18	native tissue repair? A. Yes, I did. Yes, I still do. Q. Because you wouldn't have	e
 16 also use the AMS kit? 17 A. No, I think I was mostly us 18 the Prolift kit. 19 Q. But you were trained on Al 	iing	16 17 18 19	native tissue repair? A. Yes, I did. Yes, I still do. Q. Because you wouldn't have recommended that and done that procedur	e
16 also use the AMS kit? 17 A. No, I think I was mostly us 18 the Prolift kit. 19 Q. But you were trained on Al 20 Perigee and Apogee also?	ing MS	16 17 18 19 20	native tissue repair? A. Yes, I did. Yes, I still do. Q. Because you wouldn't have recommended that and done that procedur in approximately half of the women if you	e
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16 also use the AMS kit? 17 A. No, I think I was mostly us 18 the Prolift kit. 19 Q. But you were trained on Al 20 Perigee and Apogee also? 21 A. Yeah, so if companies were 22 willing to train me and I can get	iing MS	16 17 18 19 20 21 22	native tissue repair? A. Yes, I did. Yes, I still do. Q. Because you wouldn't have recommended that and done that procedur in approximately half of the women if you were having poor results, right? A. Correct.	e
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	Page 42			Page 44
1	switched a hundred percent over, but when	1	do offer	
2	you would have made the switch to using	2	MR. ROSENBLATT: Slow down.	
3	the Boston Scientific kit as opposed to	3	A. This is an easy question for me.	
4	the Prolift kit?	4	MR. ROSENBLATT: You can	
5	A. What year?	5	continue your answer. I just wanted	
6	Q. Or when.	6	you to slow down for the court	
7	A. I tried to go back to figure	7	reporter.	
8	this out, to be honest with you.	8	A. And I still offer transvaginal	
9	Do you know when the Boston	9	mesh procedures to patients.	
10	Scientific Pinnacle kit came out?	10	Q. When you're doing the	
11	Q. I don't know.	11	laparoscopic, what mesh product are you	
12	Do you think that's	12	using?	
13	approximately when you would have	13	A. Predominantly the Boston	
14	switched?	14	Scientific Upsylon Y-mesh.	
15	 A. That would give me at least a 	15	Q. And whether you're offering a	
16	reasonable base to figure it out.	16	transvaginal mesh repair for prolapse	
17	I probably wouldn't have	17	today, what mesh are you using?	
18	switched day one that it came out, but I	18	A. The Boston Scientific Uphold	
19	may have transitioned over several months	19	mesh.	
20	after that. And I will just also say then	20	Q. Do you have a understanding of	
21	as part of my native tissue repairs, I	21	the mesh properties of the Upsylon Y-mesh	۱
22	consider obliterative procedures, closing	22	of the pore size or weight or any of those	
23	the vagina down, as part of the native	23	properties?	
24	tissue repair.	24	A. Yes.	
	Page 43		O Comment describe that week	Page 45
1	Q. So, breaking down your	1	Q. Can you describe that mesh,	Page 45
2	Q. So, breaking down your approximately 45 to 50 percent of the	2	please?	Page 45
2	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native	2	please? A. It's a macroporous,	Page 45
2 3 4	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as	2 3 4	please? A. It's a macroporous, quote/unquote, lightweight mesh.	Page 45
2 3 4 5	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative	2 3 4 5	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is	Page 45
2 3 4 5 6	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue?	2 3 4 5 6	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct?	Page 45
2 3 4 5 6 7	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around	2 3 4 5 6 7	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct.	Page 45
2 3 4 5 6 7 8	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around 10 percent.	2 3 4 5 6 7 8	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct. Q. It's not Boston Scientific's	Page 45
2 3 4 5 6 7 8 9	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around 10 percent. Q. For obliterative?	2 3 4 5 6 7 8 9	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct. Q. It's not Boston Scientific's first prolapse mesh they've introduced,	Page 45
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2 3 4 5 6 7 8 9 10 11	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around 10 percent. Q. For obliterative? A. Yeah, somewhere around there. Again, these are gross	2 3 4 5 6 7 8 9 10 11	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct. Q. It's not Boston Scientific's first prolapse mesh they've introduced, right? A. Not that I'm not that I'm	Page 45
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around 10 percent. Q. For obliterative? A. Yeah, somewhere around there. Again, these are gross estimates. Q. So that would leave approximately 35 to 40 percent were native tissue repair? A. Okay, yeah. Q. And today what treatment options are you using for prolapse? A. So, today I we are doing both native tissue and mesh-based repair. I do laparoscopic robotic sacrocolpopexy, I do native tissue repair with uterosacral	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct. Q. It's not Boston Scientific's first prolapse mesh they've introduced, right? A. Not that I'm not that I'm aware of. Q. Is it lighter than their earlier meshes? A. I think it's yes, it's lighter than that. Q. With larger pores? A. I don't remember if it's larger pores or not. We can look at the data if we want. Q. Does it have an absorbable component to it?	Page 45
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around 10 percent. Q. For obliterative? A. Yeah, somewhere around there. Again, these are gross estimates. Q. So that would leave approximately 35 to 40 percent were native tissue repair? A. Okay, yeah. Q. And today what treatment options are you using for prolapse? A. So, today I we are doing both native tissue and mesh-based repair. I do laparoscopic robotic sacrocolpopexy, I do native tissue repair with uterosacral ligaments, with fixed spinous suspension,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct. Q. It's not Boston Scientific's first prolapse mesh they've introduced, right? A. Not that I'm not that I'm aware of. Q. Is it lighter than their earlier meshes? A. I think it's yes, it's lighter than that. Q. With larger pores? A. I don't remember if it's larger pores or not. We can look at the data if we want. Q. Does it have an absorbable component to it? A. No, it does not.	Page 45
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. So, breaking down your approximately 45 to 50 percent of the procedures that you did that were native tissue repair, do you have an estimate as to how many of those were obliterative versus the native tissue? A. I'd like to say somewhere around 10 percent. Q. For obliterative? A. Yeah, somewhere around there. Again, these are gross estimates. Q. So that would leave approximately 35 to 40 percent were native tissue repair? A. Okay, yeah. Q. And today what treatment options are you using for prolapse? A. So, today I we are doing both native tissue and mesh-based repair. I do laparoscopic robotic sacrocolpopexy, I do native tissue repair with uterosacral	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	please? A. It's a macroporous, quote/unquote, lightweight mesh. Q. It's more of a newer mesh; is that correct? A. That's correct. Q. It's not Boston Scientific's first prolapse mesh they've introduced, right? A. Not that I'm not that I'm aware of. Q. Is it lighter than their earlier meshes? A. I think it's yes, it's lighter than that. Q. With larger pores? A. I don't remember if it's larger pores or not. We can look at the data if we want. Q. Does it have an absorbable component to it?	Page 45

			1		
		Page 46			Page 48
1	mesh, do you remember or can you tell us		1	BY MR. BENTLEY:	
2	any of the mesh properties with that		2	Q. Doctor, I'm handing you what has	
3	product?		3	been marked as Exhibit 6. This is a	
4	A. It's also a macroporous		4	document that was produced to us with	
5	monofilament wide pore mesh.		5	Bates 00411900.	
6	Q. What percent of the women you		6	Do you see that?	
7	treat for prolapse today do you think you		7	A. Mm-hm.	
8	use a transvaginal-based mesh repair?		8	Q. Yes?	
9	A. Less than or somewhere around		9	A. Yes, I do.	
10	maybe 5 percent, maybe less than that.		10	Q. And this is a North Shore Long	
11	Q. What percent do you think are		11	Island Jewish Health System form.	
12	laparoscopic ASC?		12	You see that on top?	
13	A. Somewhere around 30, 35 percent.		13	A. Yes.	
14	Q. Then are you still doing vaginal		14	Q. And that's the hospital you	
15	approach native tissue repair?		15	worked at?	
16	A. Yeah.		16	A. Yes.	
17	Q. Can you estimate what percent?		17	Q. Or you still work at, right?	
18	A. Whatever the rest would be the		18	A. Yes.	
19	vaginal and the obliterative.		19	Q. And it's an institutional review	
20	Q. So that would be approximately		20	board proposal cover sheet.	
21	65 percent are going to be native repairs		21	Do you see that?	
22	and in that 65 generally is going to be		22	A. Yes.	
23	obliterative and the native tissue repair?		23	Q. And the study personnel is	
24	A. Yeah, somewhere around there.		24	listed as Dr. Lind, Dr. Hall, and Dr.	
	<u> </u>			, ,	
	ı	Page 47			Page 49
1		Page 47	1	Winkler, yourself, right?	Page 49
1 2	Q. And approximately what percent	Page 47	1 2	Winkler, yourself, right? A. Correct.	Page 49
2	Q. And approximately what percent would you estimate is the obliterative?	Page 47		A. Correct.	Page 49
2	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I	Page 47	2	A. Correct.Q. And you're listed as	Page 49
2 3 4	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much.	Page 47	2	A. Correct.	Page 49
2 3 4 5	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this	Page 47	2 3 4 5	A. Correct.Q. And you're listed as subinvestigator; is that correct?A. Correct.	Page 49
2 3 4	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of	Page 47	2 3 4	A. Correct.Q. And you're listed as subinvestigator; is that correct?A. Correct.Q. And the protocol title is	
2 3 4 5 6 7	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse	Page 47	2 3 4 5 6 7	 A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh" 	
2 3 4 5 6	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair?	Page 47	2 3 4 5 6	 A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." 	
2 3 4 5 6 7 8	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair?	Page 47	2 3 4 5 6 7 8	 A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? 	
2 3 4 5 6 7 8	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right.	Page 47	2 3 4 5 6 7 8 9	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that?	
2 3 4 5 6 7 8 9	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs	Page 47	2 3 4 5 6 7 8 9 10	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do.	
2 3 4 5 6 7 8 9 10 11	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective?	Page 47	2 3 4 5 6 7 8 9 10 11	 A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was 	
2 3 4 5 6 7 8 9 10 11 12	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes.	Page 47	2 3 4 5 6 7 8 9 10 11 12	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002.	
2 3 4 5 6 7 8 9 10 11 12 13	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your	Page 47	2 3 4 5 6 7 8 9 10 11 12 13	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do.	
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I	
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today?	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today? A. From what I'm aware of, yes.	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today?	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003. But once again, I didn't sign off on this	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today? A. From what I'm aware of, yes. (Exhibit Winkler 6, North Shore LIJ Institutional Review Board	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003. But once again, I didn't sign off on this piece of paper.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today? A. From what I'm aware of, yes. (Exhibit Winkler 6, North Shore LIJ Institutional Review Board Proposal Cover Sheet, Bates No.	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003. But once again, I didn't sign off on this piece of paper. Q. Do you recall being a	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today? A. From what I'm aware of, yes. (Exhibit Winkler 6, North Shore LIJ Institutional Review Board	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003. But once again, I didn't sign off on this piece of paper.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And approximately what percent would you estimate is the obliterative? A. Probably around 10 percent. I don't think that has changed much. Q. So if my math is correct at this point, that's approximately 55 percent of the women you're treating for prolapse today you're doing a native tissue repair? A. That's probably about right. Q. Do you feel that those repairs are safe and effective? A. Yes. Q. From what you've discussed with your patients and heard about your patients, are they satisfied and happy with the native tissue repairs that you're performing today? A. From what I'm aware of, yes. (Exhibit Winkler 6, North Shore LIJ Institutional Review Board Proposal Cover Sheet, Bates No. ETH.MESH.00411090, was marked for	Page 47	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Correct. Q. And you're listed as subinvestigator; is that correct? A. Correct. Q. And the protocol title is "Clinical Evaluation of Gynecare Gynemesh for Pelvic Floor Repair." Do you see that? A. Yes, I do. Q. And the proposed start date was November 22nd, 2002. Do you see that? A. Yes, I do. I don't know how we got that proposed start date when it's when - I didn't sign off on this - when my partner signed off on that on March 27th, 2003. But once again, I didn't sign off on this piece of paper. Q. Do you recall being a subinvestigator in this study regarding	

Page 50 Page 52 1 investigator paperwork on -- on this, no. 1 in the top right. 2 Q. So, aside from filling out the 2 Do you see that? 3 paperwork, do you remember being part of 3 Correct. Α. 4 this study --4 Q. The form notes that the last 5 So, I didn't fill out this 5 visit date was December 18th, 2002. Α. 6 6 Do you see that? paperwork. 7 7 Let's see. Where? Q. So, that aside, noting that you Α. 8 didn't fill out the paperwork, do you 8 Q. In the date on the top right. 9 remember participating or being a part of 9 Show me where. 10 the study in 2002? 10 I think you turned the page. A. I don't remember what this study I'm on Bates 103. It's the second page in 11 11 12 entailed and what we actually did on it in 12 the document. the end, if we did any work on it. 13 13 Α. Okay. Q. It wouldn't have been unusual 14 14 Q. Do you see that the protocol 15 for you to participate in a study like 15 name is "Clinical Evaluation of Gynemesh Gynemesh PS for Pelvic Floor Repair"? this with Dr. Lind though, right? 16 16 No, it wouldn't have been, and Correct. 17 17 Α. 18 he probably would have put my name on it 18 And under the middle box it Q. because I was doing these procedures, as 19 19 says: "Study staff present." 20 was Dr. Hall back then. 20 Do you see that? 21 Q. When you're updating your CV in 21 A. Yes, I do. 22 2013, if you had been provided with Q. And you're listed again as a 22 23 paperwork indicating that you were a 23 subinvestigator; is that correct? 24 subinvestigator in a study to evaluate 24 That's correct. Page 51 Page 53 Gynemesh for pelvic floor repair, is that 1 Q. And towards the bottom of the 1 2 the type of information you would have 2 page it notes that the study's continuing 3 3 liked to have added with your CV? and your group has entered to date 12 4 If I would have known about it, 4 patients. 5 5 I would have added it. Do you see that? 6 This was ten years before. So, 6 That's correct. 7 you know, either I didn't remember it or 7 It appears on Bates 105 that this was just a proposal and it never 8 8 someone came out to visit the site to see 9 9 happened. I don't know. if the study was still going on and they I'm going to hand you what's 10 signed it in 2004. 10 been marked as Exhibit 7. 11 Α. Okav. 11 (Exhibit Winkler 7, Monitoring So based off your review of this 12 12 document, does it indicate that you were 13 Reports, Bates No. ETH.MESH.00411100 13 through ETH.MESH.00411113, was marked at least listed as a subinvestigator in a 14 14 15 for identification, as of this date.) Gynemesh PS study in 2004? 15 16 BY MR. BENTLEY: 16 Α. 17 O. This is a monitoring report with 17 Does this refresh your memory at 0. Bates 411102. 18 18 all? 19 If you'll turn to the second 19 I don't remember this page you can see the document is titled independently. If I would have remembered 20 20 it, I would have put it on my CV. If we 21 "Clinical Site Monitoring Visit Report." 21 22 Do you see that? 22 did a study, I put on it. 23 Yes. 23 Once again, I did this format in Α. 24 And it's dated March 10th, 2004 24 2011, 2012, and this study closed in, you

Page 56 Total total me, December of when did you tell me that it closed? 2 1 1 1 2 2 2 2 2 3 3 2 3 3				,	
tell me that it closed? Q. I don't think we've seen that 4 yet. So I'm going to hand you what's 5 being marked as Exhibit 8. (Exhibit Winkler 8, Clinical 8 Evaluation of Gynecare GyneMesh PS 9 Mesh for Pelvic Floor Repair Clinical 10 Study, was marked for identification, 11 as of this date.). 12 THE WITNESS: Okay. 13 MR. BENTLEY: And this is 14 another document that was produced to 15 us. I'm not sure why the Bates is not 16 on there. We can, for the record, 17 submit a Bates labeled copy as needed. 18 And this is the Clinical 19 Evaluation of Gynecare Gynemesh PS 20 Mesh For Pelvic Floor Repair a 21 Clinical Study, 22 BY MR. BENTLEY: 23 Q. Do you see that? 24 A. Yes, I do. Page 57 2 I Q. And it appears that the study 2 was completed and results were collected 3 and this is a summary of that study. 4 Is that a fair recitation 5 A. That's correct, fair. 6 Q. I suspect you still don't remember participating in the study based off this document? A. That's correct, fair. 6 Q. And these documents weren't provided to you in your preparation for this report in this litigation; is that ornect? 10 Q. And those this before today. 10 Q. And twee done member one of the study is a principal investigator; is that correct? 11 A. Yes, I do a 12 the principal investigator; is that I a. A. Yes, os, some of the ways that I be wold remember some of the studf is I do a Pub Med search, and I don't know if this ever are me up on a Pub Med search for yourself? 1 A. Yeal. Listen, I had to go back eight years. 13 Q. Let's put that aside and look at 14 your report. 15 So, I believe we marked 16 Exhibit 2 as your report entitled "Expert 17 Report of Harvey Winkler MD Regarding 18 Gynemesh and Prolific." 19 Is that correct, Exhibit 2 is 20 your report? 21 A. Yes. 22 Q. And this report has a number of footnotes at the end on page 46; is that 23 footnotes at the end on page 46; is that 24 (a. Yes, it does. 25 Q. And on page 41; it indicates that 26 you signed this report on Tebruary 5th, 27 year for the wind in the study of the p		Page 54			Page 56
3 Q. I don't think we've seen that 4 yet. 5 So I'm going to hand you what's 6 being marked as Exhibit 8. 7 (Exhibit Winkler 8, Clinical 8 Evaluation of Gynecare GyneMesh PS 9 Mesh for Pelvic Floor Repair Clinical 10 Study, was marked for identification, 11 as of this date.) 11 THE WITNESS: Okay. 12 THE WITNESS: Okay. 13 MR. BENTLEY: And this is 14 another document that was produced to 15 us. I'm not sure why the Bates is not 16 on there. We can, for the record, 17 submit a Bates labeled copy as needed. 18 And this is the Clinical 19 Evaluation of Gynecare Gynemesh PS 10 Wesh For Pelvic Floor Repair a 21 Clinical Study. 21 BY MR. BENTLEY: 22 BY MR. BENTLEY: 23 Q. Do you see that? 24 A. Yes, I do. 25 Page 57 26 Q. And it appears that the study was completed and results were collected and this is a summary of that study. 3 Is that a fair recitation	1	just told me, December of when did you	1	other studies where you're not necessarily	
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1 Q. And some of the literature you were already familiar with, correct? 2 were already familiar with, correct? 3 A. Yes. 4 Q. And some of that literature was provided to by Ethicon; is that correct? 5 A. Correct. And then 1 did my own searches as well. 9 Q. And you also reviewed some of plaintiff's reports and their materials that they cited, correct? 10 A. Correct. 11 A. Correct. 12 Q. And taking that large basket of studies and literature, again you didn't do any independent statistical analysis to somehow combine all that information into one calculation or anything, right? 18 Q. So, again you're going to rely upon Level I evidence that it's a systematic review of other studies 21 performed by the statistical experts that crunch numbers; is that fair? 23 A. That's fair. 24 Q. Okay. And so, using the Oxford 2 Levels of Evidence that we've discussed today, Level I is going to be the systematic review and that's the highest level of evidence, correct? 3 A. That's fair. 4 Q. Okay. And so, using the Oxford 4 I Levels of Evidence that we've discussed today, Level I is going to be the systematic review and that's the highest level of evidence, correct? 5 A. Correct. 6 Q. And we've previously discussed today the correct review, of the Corrane reviews, and that's the highest level of evidence, correct? 5 A. Correct. 6 Q. And we've previously discussed today that you would a hundred percent rely on one particular study. I try to take them all in context. 6 Q. And we've previously discussed to evidence in this situation also? 1 Levels of Evidence that we've discussed to day. Level I is going to be the systematic review and that's the highest level of evidence, correct? A. Torect. 9 A. That's fair. 20 Q. So, again you're going to rely that they to that fair? 21 Levels of Evidence that we've discussed to day. Level I is going to be the systematic review and that's the highest level of evidence, correct? 4 Q. Okay. And so, using the Oxford 1 Levels of Evidence that we've discussed to day. Level I is going to be the						
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8 Q. And you also reviewed some of 9 plaintiff's reports and their materials 10 that they cited, correct? 11 A. Correct. 12 Q. And taking that large basket of 13 studies and literature, again you didn't 14 do any independent statistical analysis to 15 somehow combine all that information into 16 one calculation or anything, right? 17 A. No, I did not. 18 Q. So, again you're going to rely 19 upon Level I evidence that it's a 19 systematic review of other studies 20 systematic review of other studies 21 performed by the statistical experts that 22 crunch numbers; is that fair? 23 A. That's fair. 24 Q. Okay. And so, using the Oxford 25 today, Level I is going to be the 26 systematic review and that's the highest 27 level of evidence, correct? 28 A. Correct. 29 A. Correct. 20 A. Correct. 30 Systematic review and that's the highest 41 level of evidence, correct? 5 A. Correct. 6 Q. And we've previously discussed 6 Some of the Cochrane reviews, and I think 7 you said that you would a hundred percent 7 rely on those. 9 Is that fair regarding your 10 Prolift report also? 11 Prolift report also? 12 A. I don't know if I hundred 13 A. I don't know if I hundred 14 percent rely on one particular study. I the ty take them all in context. 15 (O. So, you would definitely put the 16 cochrane reviews as the highest level of evidence in this situation also? 19 A. It's one of the types of the 19 thighest levels, yes. 10 Q. And is there any reason you 21 wouldn't a hundred percent rely on the evidence in this situation also? 22 cochrane review as you sit here today why to mode handred percent rely on the cochrane reviews. 25 Cochrane review as you sit here today that 26 Cochrane reviewed as you sit here today why reason today why to the hold and rely on a hundred percent. 26 Q. If you had any criticism of that study as you sit here today? 27 A. I don't -1'I dlike to see the study be included in your report? 28 A. N						- 1
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9 plaintiff's reports and their materials 10 that they cited, correct? 11 A. Correct. 12 Q. And taking that large basket of 13 studies and literature, again you didn't 14 do any independent statistical analysis to 15 somehow combine all that information into 16 one calculation or anything, right? 17 A. No, I did not. 18 Q. So, again you're going to rely 19 upon Level I evidence that it's a 20 systematic review of other studies 21 performed by the statistical experts that 22 crunch numbers; is that fair? 23 A. That's fair. 24 Q. Okay. And so, using the Oxford 25 Levels of Evidence that we've discussed 26 today, Level I is going to be the 27 systematic review and that's the highest 28 level of evidence, correct? 3 A. Correct. 4 level of evidence, correct? 5 A. Correct. 5 A. Correct. 6 Q. And we've previously discussed 7 some of the Cochrane reviews, and I think 8 you said that you would a hundred percent 10 rely on a hundred percent 11 read and that's to the only thing that I 12 would rely on a hundred percent 14 do ony independent statistical experts that 15 would rely on a hundred percent 16 op a hundred percent rely and a hundred percent rely and any criticism of that study as 17 you sit here today? 18 A. I don't 'I'd like to see the 19 upon Level I evidence that we've discussed 20 performed by the statistical experts that 21 that study, would they be included in your 22 report? 23 A. Not necessarily. 24 Q. So, does your report contain a 25 report? 26 A. Not necessarily. 27 A. Not necessarily. 28 A. Not necessarily. 29 C. So, does your report contain a 29 true and accurate list of all of your 20 opinions you intend to offer at trial for 21 true and accurate list of all of your 22 opinions you intend to offer at trial for 23 systematic review and that's the highest 24 level of evidence, correct? 25 A. Correct. 26 A. Correct. 27 Some of the Cochrane reviews, and I think 28 you sit here today? 29 A. Not necessarily. 20 C. So, you would a hundred percent 21 true and accurate list of all of your 22 opinions you	8	Q. And you also reviewed some of		8	Q. But regardless, is there any	
that they cited, correct? A. Correct. Q. And taking that large basket of studies and literature, again you didn't do any independent statistical analysis to somehow combine all that information into somehow combine all that information into one calculation or anything, right? A. No, I did not. Q. So, again you're going to rely upon Level I evidence that it's a systematic review of other studies 20 systematic review of other studies 22 crunch numbers; is that fair? A. That's not the only thing that I would rely on a hundred percent. Q. I see what you're saying. The 2016 Maher Cochrane review, do you have any criticism of that study as you sit here today? A. I don't I'd like to see the study before I criticize it. Q. If you had any criticisms of that study, would they be included in your report? A. That's fair. 22 rounch numbers; is that fair? 23 A. That's fair. 24 Q. Okay. And so, using the Oxford Page 59 1 Levels of Evidence that we've discussed today, Level I is going to be the systematic review and that's the highest level of evidence, correct? A. Correct. Q. And we've previously discussed some of the Cochrane reviews, and I think you said that you would a hundred percent rely on one particular study. I try to take them all in context. Q. So, you would definitely put the Cochrane reviews as the highest level of evidence in this situation also? A. It's one of the types of the bighest level of evidence in this situation also? A. It's one of the types of the bighest level of evidence in this situation also? A. It's one of the types of the bighest level of evidence in this situation also? A. It's one of the types of the bighest level of evidence in this situation also? A. As new evidence becomes available when you wrote this report, right? A. Yes. MR. ROSENBLATT: And there are several Maher 2016 Cochrane reviews. So I just want to make sure you're referring to vaginal prolapse as opposed to apical repair. Just because there are multiple ones, I want to make sure you guys are talking		- ,		9	- · · · · · · · · · · · · · · · · · · ·	
11 A. Correct. Q. And taking that large basket of 12 studies and literature, again you didn't 13 studies and literature, again you didn't 14 do any independent statistical analysis to 15 somehow combine all that information into 16 one calculation or anything, right? 17 A. No, I did not. 18 Q. So, again you're going to rely 19 upon Level I evidence that it's a 20 systematic review of other studies 21 performed by the statistical experts that 22 crunch numbers; is that fair? 23 A. That's fair. 24 Q. Okay. And so, using the Oxford 25 Levels of Evidence that we've discussed 26 today, Level I is going to be the 27 systematic review and that's the highest 28 level of evidence, correct? 29 A. Correct. 20 Q. And we've previously discussed 21 some of the Cochrane reviews, and I think 29 you sit here today? 29 And we've previously discussed 20 today, Level I is going to be the 21 some of the Cochrane reviews, and I think 29 you sid that you would a hundred percent 20 report? 21 Prolift report also? 22 A. Not necessarily. 23 A. Not necessarily. 24 Q. So, does your report contain a 25 true and accurate list of all of your 26 opinions you intend to offer at trial for 27 the jury regarding the Prolifit and the 28 sufficiency of the Cochrane reviews, and I think 29 you sid that you would a hundred percent 20 report? 21 report also? 22 A. Not necessarily. 23 A. It don't if if remember 24 level of evidence, correct? 25 A. Correct. 26 Q. And we've previously discussed 27 some of the Cochrane reviews, and I think 28 you said that you would a hundred percent 29 report report and accurate list of all of your 20 princips you intend to offer at trial for 20 true and accurate list of all of your 21 opinions you intend to offer at trial for 22 true and accurate list of all of your 23 opinions you intend to offer at trial for 24 true and accurate list of all of your 25 opinions you intend to offer at trial for 26 true and accurate list of all of your 27 opinions you intend to offer at trial for 28 true and accurate list of all of your		·				
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16 one calculation or anything, right? A. No, I did not. 20. So, again you're going to rely 19 upon Level I evidence that it's a 20 systematic review of other studies 21 performed by the statistical experts that 22 crunch numbers; is that fair? 23 A. That's fair. 24 Q. Okay. And so, using the Oxford Page 59 1 Levels of Evidence that we've discussed 25 today, Level I is going to be the 26 systematic review and that's the highest 27 systematic review and that's the highest 28 level of evidence, correct? 29 A. Correct. 20 O. If you had any criticize it. 21 that study, would they be included in your report. 22 report? 23 A. Not necessarily. 24 Q. So, does your report contain a Page 59 1 true and accurate list of all of your opinions you intend to offer at trial for the jury regarding the Prolift and the level of evidence, correct? 4 G. And we've previously discussed some of the Cochrane reviews, and I think you said that you would a hundred percent rely on those. 4 Is that fair regarding your 4 Prolift report also? 5 A. I don't know if I hundred 13 A. A snew evidence becomes available? 4 In the purp regarding the Prolift and the level of evidence, correct? 5 A. Correct. 6 Q. And we've previously discussed some of the Cochrane reviews, and I think you said that you would a hundred percent rely on those. 9 Q. As new evidence becomes available? 10 A. As new evidence becomes available? 11 A. B. A some evidence becomes available when you wrote this report, right? 12 available when you wrote this report, right? 13 A. Not necessarily. 24 D. So, does your report contain a Page 61 25 True and accurate list of all of your opinions you intend to offer at trial for the jury regarding the Prolift and the gynemesh PS? 2 A. It does, but if I remember correctly, even in my report, I reserve the right to modify opinions as I learn stuff. 26 Q. As new evidence becomes available? 27 A. As new evidence becomes available? 28 A. I don't know if I hundred 19 A. As new evidence becomes available when you wrote this report, right? 3						
17	15	somehow combine all that information into		15	The 2016 Maher Cochrane review,	
17	16	one calculation or anything, right?		16	do you have any criticism of that study as	
18 Q. So, again you're going to rely upon Level I evidence that it's a 20 systematic review of other studies 20 Q. If you had any criticism of 21 performed by the statistical experts that 22 crunch numbers; is that fair? 23 A. That's fair. 23 A. That's fair. 24 Q. Okay. And so, using the Oxford 24 Q. So, does your report contain a 25 page 59 1 Levels of Evidence that we've discussed 27 today, Level I is going to be the 28 systematic review and that's the highest 29 today, Level I is going to be the 39 systematic review and that's the highest 4 level of evidence, correct? 4 Gynemesh PS? 5 A. Correct. 5 A. Correct. 5 A. Correct. 5 A. Correct. 5 A. It does, but if I remember 29 correctly, even in my report, I reserve 39 the right to modify opinions as I learn 39 the rely on those. 9 Q. As new evidence becomes 30 Is that fair regarding your 30 A. I don't know if I hundred 31 Prolift report also? 4 A. It don't know if I hundred 31 Percent rely on one particular study. I 15 try to take them all in context. 15 right? 4 Q. So, you would definitely put the 20 Cochrane reviews as the highest level of evidence in this situation also? 18 So I just want to make sure you're referring to vaginal prolapse as opposed to apical repair. Just because there are multiple ones, I 22 wouldn't a hundred percent rely on the 22 because there are multiple ones, I 22 want to make sure you guys are talking						
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Page 62 Page 64 1 (Exhibit Winkler 9, Maher 1 A. Well, I'd have to go over their 2 Cochrane review, was marked for 2 search methods and review it. I'm not --3 identification, as of this date.) 3 so, I -- and I haven't done that. 4 4 BY MR. BENTLEY: MR. BENTLEY: Let me rephrase 5 Doctor, I'm handing you what is 5 it. 6 marked as Exhibit 9, which is a Cochrane 6 BY MR. BENTLEY: 7 review entitled "Transvaginal mesh or 7 Q. In your report, you don't 8 grafts compared with native tissue repair 8 identify any problems with the Cochrane 2016 review such that they failed to 9 for vaginal prolapse." 9 include some studies that you think they 10 Do you see that? 10 Okay. Yes, I have it. should have included? 11 A. 11 And we were discussing the 12 12 A. I did not include that in my 13 Cochrane reviews are a Level I evidence, report. However, it's possible that they 13 missed some studies or should have 14 right? 14 15 Α. Yes. 15 included some studies. And I was asking as you sit here 16 Q. And in your report, similarly 16 today, do you have any criticisms or you don't identify any methodological 17 17 18 reasons to not rely upon the latest 18 criticisms with the Cochrane 2016 review Cochrane review regarding Prolift and performed, with their meta-analysis 19 19 mesh-based repairs for prolapse? combining several RCTs and generating 20 20 Once again, I don't rely on just various complication rates? You don't 21 21 one study for an opinion whether or not to 22 have any criticisms of the methodology 22 23 do and use a surgical procedure and a 23 they employed to make their meta-analysis, 24 device. 24 do you? Page 63 Page 65 So other than the fact that you 1 Currently, I don't have any 1 A. don't rely upon one study, do you have any 2 2 criticisms. other reasons not to rely upon this study 3 3 Q. And you didn't disclose any in 4 or criticisms of this study? 4 your report, right? MR. ROSENBLATT: Object to form. 5 5 A. I did not disclose any in my 6 If you want to skim through it 6 report. 7 or ask if he has any criticisms about 7 You would agree that the 2016 Cochrane review is one of the most a particular section, that might be 8 8 9 9 easier, but that's just very broad. powerful and reliable sources of data 10 BY MR. BENTLEY: 10 available? 11 Q. Well, first, Doctor, do you 11 A. I think it's one of the reliable understand the question? 12 12 sources available. I guess most powerful 13 A. Do I have any criticisms of the 13 is subjective. 14 Q. And by powerful, I mean they study? 14 have reviewed expansive number of studies, 15 15 Yes. Q. 16 Is the question. 16 had a preset inclusion/exclusion criteria, Overall, I accept its findings. had a preset methodological analysis and 17 17 I have not reviewed part-by-part every performed meta-analysis to combine those 18 18 single methodology that they have 19 19 studies. 20 performed. 20 Is that fair? 21 Q. Okay. Do you have any -- do you 21 A. Fair enough. know of any studies that they didn't 22 22 And that's what constitutes included in their analysis that they 23 23 Level I evidence, is someone that 24 should have? 24 undertakes that type of statistical

	Pa	ige 66		Page 68
1	analysis?		1	with lower rates of awareness of prolapse,
2	A. Fair enough.		2	reoperation for prolapse and prolapse on
3	MR. ROSENBLATT: Greg, we've		3	examination than native tissue repair is
	been going about an hour. I don't		4	•
4				also associated with higher rates of
5	want to cut you off.		5	reoperation for prolapse, stress urinary
6	MR. BENTLEY: It's good. We can		6	incontinence, or mesh exposure and higher
7	take a break.		7	rates of bladder injury at surgery and
8	(Recess taken from 5:09 p.m. to		8	de novo stress urinary incontinence."
9	5:17 p.m.)		9	Do you see that?
10	BY MR. BENTLEY:		10	A. I got to be honest with you, no.
11	Q. All right, Doctor. We are back		11	Q. We're on page 2 under "Author
12	from a break.		12	Conclusions."
13	Are you ready?		13	A. Okay.
14	A. Yeah.		14	•
				- , ,
15	Q. We were discussing the 2016		15	conclusion, you don't discuss that
16	Cochrane review from Maher regarding		16	conclusion in your report; is that
17	transvaginal mesh for prolapse repair.		17	correct?
18	Do you remember that?		18	A. That's not true, I think.
19	A. Yes.		19	MR. ROSENBLATT: Take as much
20	Q. And we just entered that review		20	time as you need to look through your
21	as an exhibit, I think it's Exhibit 9; is		21	report.
22	that correct?		22	(Pause.)
23	A. That is correct.		23	BY MR. BENTLÉY:
24	Q. You discussed this review in		24	Q. So, on page 20 and 21, you don't
	•			ξ. σογ σ μαζο = σ αα ==, γ σα ασ σ
	Pa	ige 67		Page 69
1		ige 67	1	
1 2	your report several places.	ige 67	1 2	mention those conclusions; is that
2	your report several places. If you turn to page 20 in your	ige 67	2	mention those conclusions; is that correct?
2	your report several places. If you turn to page 20 in your report, I believe it's the first time you	ige 67	2	mention those conclusions; is that correct? A. I'm looking, sorry.
2 3 4	your report several places. If you turn to page 20 in your report, I believe it's the first time you mention this review.	ge 67	2 3 4	mention those conclusions; is that correct? A. I'm looking, sorry. Q. That's fine.
2 3 4 5	your report several places. If you turn to page 20 in your report, I believe it's the first time you mention this review. A. Okay.	ge 67	2 3 4 5	mention those conclusions; is that correct? A. I'm looking, sorry. Q. That's fine. A. Really.
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2 3 4 5 6 7 8	your report several places. If you turn to page 20 in your report, I believe it's the first time you mention this review. A. Okay. Q. And at the bottom of page 20 you note that this is the most recent review, and it shows good objective and subjective	ge 67	2 3 4 5 6 7 8	mention those conclusions; is that correct? A. I'm looking, sorry. Q. That's fine. A. Really. (Pause.) A. So, I did note that there were recurrence the recurrence and rates of
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		Page 70		F	Page 72
1	agree with that conclusion?		1	goals and expectations from the surgical	, I
2	A. I think that depends on the		2	procedure. And I think that's what it's	
3	patient, and I understand when you're		3	pertaining to, in my opinion.	
4	doing it on thousands of patients and		4	Q. The authors continue in the	
	•			•	
5	younger patients that it may not be the		5	Cochrane review: "While it is possible	
6	first type of repair that you're doing,		6	that in women with higher risk of	
7	but it may be a primary repair in certain		7	recurrence the benefits may outweigh the	
8	types of patients. So basically it's		8	risks, there's currently no evidence to	
9	saying is that you shouldn't do a		9	support this deposition."	
10	transvaginal mesh repair in everybody,		10	Do you see that?	
11	especially in patients in primary		11	A. Page 2?	
12	surgeries, and I've always agreed with		12	Q. Yes, the last sentence of that	
13	that.		13	paragraph in the conclusion.	
14	Q. So you would agree that there's		14	A. Based on this review, I will	
15	limited utility for the transvaginal mesh		15	agree.	
16	•		16	5	
	in primary surgery for repair of prolapse?			However, once again, in specific	
17	A. I think the word "limited" is a		17	patients who have recurrence, and if you	
18	tough answer to question to answer.		18	look at the ACOG guidelines, the ACOG has	
19	So, I think in the patient who's		19	guidelines that mesh may be, and if we can	
20	80 years old with a prolapse surgery and		20	pull them out that would be even better,	
21	who's not sexually active and wants a		21	may be appropriate for patients with	
22	minimally invasive procedure, it may have		22	recurrence.	
23	very good utility in those patients.		23	Q. For limited patients that are	
24	I understand what you're trying		24	suffering from recurrence, transvaginal	
	· · · · · ·			<u> </u>	
		Page 71		F	Page 73
1	to say in limited utility in sort of	Page 71	1		Page 73
1 2	to say in limited utility in sort of everybody, but there are patients that	Page 71	1 2	mesh may be appropriate in that situation.	Page 73
2	everybody, but there are patients that	Page 71	2	mesh may be appropriate in that situation. Is that consistent	Page 73
2	everybody, but there are patients that transvaginal mesh is appropriate for, in	Page 71	2	mesh may be appropriate in that situation. Is that consistent A. Repeat that again?	Page 73
2 3 4	everybody, but there are patients that transvaginal mesh is appropriate for, in my opinion, and there are patients that it	Page 71	2 3 4	mesh may be appropriate in that situation. Is that consistent A. Repeat that again? Q. Transvaginal mesh may be	Page 73
2 3 4 5	everybody, but there are patients that transvaginal mesh is appropriate for, in my opinion, and there are patients that it may not be appropriate for, in my opinion.	Page 71	2 3 4 5	mesh may be appropriate in that situation. Is that consistent A. Repeat that again? Q. Transvaginal mesh may be appropriate for patients that suffer from	Page 73
2 3 4 5 6	everybody, but there are patients that transvaginal mesh is appropriate for, in my opinion, and there are patients that it may not be appropriate for, in my opinion. Q. So let's narrow that down.	Page 71	2 3 4 5 6	mesh may be appropriate in that situation. Is that consistent A. Repeat that again? Q. Transvaginal mesh may be appropriate for patients that suffer from recurrence, that may be the appropriate	Page 73
2 3 4 5 6 7	everybody, but there are patients that transvaginal mesh is appropriate for, in my opinion, and there are patients that it may not be appropriate for, in my opinion. Q. So let's narrow that down. You would agree that	Page 71	2 3 4 5 6 7	mesh may be appropriate in that situation. Is that consistent A. Repeat that again? Q. Transvaginal mesh may be appropriate for patients that suffer from recurrence, that may be the appropriate treatment for prolapse in that situation;	Page 73
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Page 74 Page 76 risk." I don't know if I could say that for each 1 1 2 2 particular type of patient. If a patient And that's the subgroup that 3 3 you're talking about where Prolift and has a primary prolapse with a bad history 4 4 Gynemesh PS is the appropriate repair, of intra-abdominal adhesions, bowel 5 right? 5 obstructions or many reasons why I 6 6 A. It could be an appropriate wouldn't want to go and place an abdominal 7 repair in one of those patient 7 mesh, that may be an appropriate patient 8 8 populations. for a transvaginal mesh. 9 9 O. And the Cochrane review looked So generally you would agree 0. that the risk-benefit profile means that 10 at that and concluded there's currently no 10 evidence to support this position. That's transvaginal mesh like Prolift and 11 11 Gynemesh PS has limited utility in primary 12 their conclusion, right? 12 But they're also saying it may surgery, but there may be exceptions based 13 13 be possible then that the benefits may on an individual patient where it's 14 14 15 outweigh the risks. 15 appropriate and not exception; is that 16 There's a possibility, but 16 correct? there's currently no evidence to support 17 17 A. Yeah, there are certain patients 18 that; is that correct? 18 where I do not believe it has limited 19 A. There's no evidence that the 19 benefit and there are major benefits. 20 Cochrane review looked through -- I'm 20 And can I comment that's why 522 trying to remember if there was a paper 21 21 studies are being performed today to 22 that specifically looked at recurrence. I decide whether or not there is a benefit 22 23 think there was. 23 or not. 24 Well, I'm sure counsel will 24 Q. It's your testimony that Q. Page 75 Page 77 bring that up if we have that. 1 Ethicon's performing 522 studies today on 1 2 2 Okav. Prolift or Gynemesh PS for prolapse? Α. 3 Nope, it's not my -- it's not my 3 But staying on the Cochrane 4 review, which is the Level I evidence, the 4 testimony at all. 5 highest level of evidence, right? 5 My testimony is that there are 6 A. Correct. 6 522 studies being performed to ascertain 7 7 whether or not transvaginal mesh is an Q. And these authors looked at a 8 acceptable form of treatment in patients 8 lot of studies. We can look at the 9 9 methods, and we will. with -- for patients with primary surgery. 10 And based off of their review, 10 Q. That's happening today for 11 they concluded that there's no evidence to 11 Ethicon products? even support that limited possibility; is Once again, I said it's not for 12 12 Ethicon products, but for transvaginal 13 that correct? 13 mesh. The Cochrane review is not only for 14 A. They accepted that it's 14 possible, but they did not find any 15 Ethicon products. It's on all 15 16 evidence to support it, correct. 16 polypropylene meshes that are placed Ultimately they decided that the 17 17 transvaginally. risk-benefit profile means transvaginal Q. On the previous page under the 18 18 mesh has limited utility in primary main results of the abstract, do you see a 19 19 20 section, Doctor? surgery. 20 Previous page, page 1? 21 And is that consistent with your 21 Α. 22 22 opinion here? Yes. Q. 23 A. Overall, I would say that, but 23 Yes, I do. Α. 24 on a patient-specific type of discussion, 24 They note under "Main Results"

Page 78 Page 80 1 that they included 37 RCTs. 1 opinion as to what acceptable rates of 2 Do you see that? 2 complications were. 3 3 Yes. Do you remember? Α. Yes, I do. 4 That's a fairly large number of 4 Q. 5 randomized control trials to include, 5 And similarly, here in your 6 report you cite a number of different would vou agree? 6 7 A. I would agree that's a good 7 studies with a fairly wide variation in 8 8 different findings, and I have some number. 9 9 Q. Would you agree that that questions. provides a powerful basis or statistical 10 10 As you sit here today, based on basis that's a powerful number of studies your review of the literature and your 11 11 clinical experience, do you have an 12 to include? 12 I think it's a good number. I estimate or an opinion as to what an 13 13 don't know if I would use the word acceptable rate of mesh exposure is on 14 14 "powerful," but I think it's an adequate prolapse repairs using mesh? 15 15 MR. ROSENBLATT: Object to form. 16 16 number. 17 BY MR. BENTLEY: 17 Q. Do you have any understanding 18 how many RCTs you used in your analysis? 18 That are transvaginally placed? Q. I didn't count up the number of 19 19 My -- in my experience, what I would think is going to occur in our 20 RCTs. 20 patient population is that somewhere 21 Turning back to page 2, there's 21 22 some summaries of their findings. I want around a 10 to 12 percent mesh exposure 22 23 to draw your attention to the last 23 rate is going to occur with a transvaginal 24 paragraph. 24 mesh. Page 79 Page 81 Do you see it starts with 1 Q. And that wasn't really my 1 2 "Permanent mesh"? Are you with me? 2 question. 3 3 Α. Yes. What's an acceptable rate of 4 4 exposure for transvaginal mesh repairs to And Maher writes: "Permanent 0. 5 5 treat prolapse, in your opinion based off mesh was associated with higher rates of 6 de novo stress incontinence." 6 of your review and your clinical 7 Do you see that? 7 experience? 8 8 A. Yes, I do. A. So, my expected rate is my 9 9 Q. And it also notes that there's a acceptable rate. higher rate of bladder injury. 10 Q. And so something, an exposure 10 11 Do you see that? 11 rate higher than 12 percent would cause Yes, I do. you concern? 12 12 Α. Q. And do you agree with those 13 13 Not necessarily. It depends on findings, that permanent mesh is what the exposure is and how symptomatic 14 14 associated with a higher rate of de novo 15 it is and what we're doing for that 15 exposure. 16 stress incontinence and bladder injury? 16 I agree that that's what has Q. Doctor, would you please turn 17 17 been seen with these procedures, yes. your attention to page 16 of the 2016 18 18 Q. Is that consistent with your Cochrane review we were looking at? 19 19 opinions in your report? 20 20 Α. Okay. 21 Α. Yeah, I think I wrote that in my 21 On the left-hand column it says: "1.2.3. Surgery for prolapse stress 22 22 report. urinary incontinence or mesh exposure." 23 Doctor, earlier in the earlier 23 24 deposition today we were discussing your 24 Do you see that?

Page 82 Page 84 1 Α. I do. 1 Well, that's what I'm saying. 2 2 So once again, if she's asymptomatic, we The authors began: "Women who 3 3 had a transvaginal mesh repair were more subsequently learned that these likely to undergo repeat surgery for asymptomatic mesh exposures are of minimal 4 4 5 prolapse stress urinary incontinence or 5 risk to the patient and we can observe and 6 mesh exposure than those undergoing native 6 watch them as opposed to taking the 7 tissue repair." 7 patient back to the operating room. 8 8 Do you see that? Because you don't want to 9 9 subject the woman to a second surgery A. I see that. 10 And you agree with that finding, 10 unless you absolutely have to, right? is that correct, that that's what this A. We wouldn't want to do surgery 11 11 12 12 that is unnecessary. shows? Because each subsequent surgery 13 A. I agree that's what they wrote, 13 has increased risks attendant to it, 14 yeah. 14 15 And as we discussed, you don't 15 right? Q. have any methodological concerns with the 16 16 A. I think every surgery has risk. Maher study, correct? 17 I don't know if you want to say each 17 18 Offhand, I do not. 18 subsequent surgery has more risk. Α. Q. Well, each time you're doing 19 And in your report, you don't 19 Q. 20 disclose any criticism of the study, 20 pelvic surgery --A. Any time you do surgery, there's 21 21 22 risk associated with it. I did criticize one thing. Let 22 Α. 23 me just check. 23 Q. And each time you do pelvic 24 (Pause.) 24 surgery, you're potentially creating more Page 83 Page 85 So, what I criticize in the 1 scar tissue in the pelvis which 1 2 study on exposure and reoperation rate is 2 complicates further surgeries; is that 3 3 that the way we managed an exposure in fair? 4 the -- in our early experience with 4 I can agree with that. Fair Α. 5 transvaginal mesh has changed dramatically 5 enough. 6 how we manage an exposure today. 6 Q. So if you can avoid it, you 7 So, initially when we were --7 don't want to perform extra surgeries on when I was and other people were 8 8 women; is that correct? 9 implanting these meshes, any time we saw 9 Α. It's correct. an exposure, we thought that needed to be 10 10 On page 16 of the Cochrane 11 treated. We subsequently learned that review on the right-hand column there's a 11 some of these exposures, and many of these Section 1.4.2 Mesh Exposure. 12 12 13 exposures are asymptomatic, and if you 13 Do you see that? have an asymptomatic exposure, you do not 14 14 Α. Yes. 15 have to treat that. 15 And they provide a finding from 16 The Cochrane review is basing 16 their analysis of 19 RCTs and they state: "Anterior repair only. Mesh exposure was 17 some of that reoperation and a lot of 17 these studies are basing their reoperation reported in 10 percent women after 18 18 anterior permanent mesh repair." 19 rates on the earlier way we managed 19 meshes, transvaginal mesh exposures. 20 20 Do you see that, the first O. And you wouldn't want to subject 21 21 bullet? 22 a woman to an additional surgery 22 Yes, I do see that. 23 unnecessarily, right, to repair an 23 And the second bullet is: 24 exposure? Is what you're saying? 24 "Multicompartment repair. Mesh exposure

Page 86 Page 88 1 was reported in 17 percent after 1 more likely to have a bladder injury than 2 multicompartment repair." 2 those with the native tissue repair? 3 3 A. I'm going to say it depends on I see that too. 4 4 how you're doing the procedure, who's Q. And 17 percent is almost 50 5 percent higher than your 12 percent 5 doing the procedure, but that's what their 6 6 acceptable rate; is that fair? data shows and I will believe that. 7 No, it's not fair. They're 7 Q. And in part, that's why you 8 putting in two pieces of mesh here. 8 think that the Prolift and Gynemesh PS 9 9 There's an anterior and a posterior piece repairs are not necessarily the primary surgical intervention for women suffering 10 of mesh. So you're going to get a 10 cumulative result from both those pieces. from prolapse; it's more of a select 11 11 O. Is it fairly common to do an group maybe with higher recurrence? Is 12 12 13 anterior and posterior repair statement? that fair? 13 A. I can't respond in how fairly 14 14 A. I think the patients you put common it is. Depends on what was going transvaginal mesh in need appropriate 15 15 16 on with the patient. counseling and discussion of putting in 16 So, your acceptable exposure the transvaginal mesh. There may be 17 17 18 rate is dependent upon whether it's 18 patients who receive more benefit from a anterior or posterior repair or a combined transvaginal mesh than others? 19 19 20 repair? 20 Q. But the risk-benefit profile 21 So, my acceptable exposure rate, 21 isn't necessarily appropriate for all 22 if you're going to do total exposure rate, women when you're doing a prolapse repair; 22 23 is going to be increased if you put in an 23 is that correct? 24 anterior and posterior piece. So 10 to 12 24 A. I would mention this to all Page 87 Page 89 percent for an anterior, 10 to 12 percent 1 woman, but depending on what their goals 1 2 for a posterior. 2 are. I mean, I mention that there's 3 3 So ultimately, do you think that transvaginal mesh to every single patient 4 the true exposure rate if you're talking 4 that comes in for a prolapse. Based on 5 about anterior and posterior repair with 5 their goals, their age, their history, 6 the Prolift or Gynemesh PS is 17 percent? 6 their sexual function, the risks of a 7 MR. ROSENBLATT: Object to form. 7 transvaginal mesh are not worth it to 8 those patients. I'll agree to that. 8 Α. Say that again. 9 9 How about what's your opinion as Q. Do you agree that the Cochrane to the actual exposure rate when you do an 10 review's conclusion is that permanent mesh 10 11 anterior and posterior repair with mesh 11 like Prolift and Gynemesh PS implanted transvaginally? vaginally has increased morbidity? 12 12 Where do you see that? 13 A. If I do both? 13 On page 29 under "Author's 14 0. Right. 14 Q. Conclusions." 15 15 If I'm doing an anterior and 16 posterior, I think you can see up to a 20 16 Α. Page 29? to 24 percent exposure rate because you're 17 17 Yes. putting in two pieces of mesh. So 10 to Generally do you agree with this 18 18 12 percent anterior, 10 to 12 percent conclusion that permanent mesh is 19 19 posteriorly. If I remember my statistics, 20 associated with increased morbidity? 20 you add them up and you get 20 to 24. 21 21 If you include mesh exposure, yes. Other than that, other complications 22 Do you agree with the Cochrane 22 review that found that women undergoing a seem to be on par with the native tissue. 23 23 24 transvaginal permanent mesh repair were 24 We've been talking about

Page 90 Page 92 1 exposure. 1 doing any extra surgery, you may think 2 2 hey, this can cause more problems. With regard to the complication 3 3 of dyspareunia, do you have an opinion as However, the data does not 4 to whether transvaginal mesh may increase 4 support that. 5 that risk as compared to native tissue 5 You're comparing Prolift and 6 6 Gynemesh PS to native tissue repair on repairs? 7 7 A. Transvaginal mesh is comparable page 30. 8 to native tissue repairs for dyspareunia. 8 Do you see that? You state 9 O. Could you please turn to page 30 9 that: "Native tissue repairs, as well as of your report? You see your paragraph 10 10 transvaginal mesh procedures like Prolift where you begin "There's no doubting," on and Gynemesh PS, can cause dyspareunia." 11 11 12 page 30? 12 A. Yes. 13 Then you state: "Intuitively we I'm sorry, you're on --13 14 A. Yeah, yeah, I want to find 14 may even reason that a transvaginal mesh something in the Cochrane review as well 15 15 procedure may increase this risk." since we've been discussing it. 16 16 So the native tissue repair, (Pause.) 17 that's going to be a foreign body that's 17 18 In the second line in that 18 implanted transvaginally, correct? 19 paragraph, you say: "Intuitively we may 19 Yes. Α. 20 even reason that transvaginal mesh 20 But you're implanting the mesh Q. 21 procedure may increase this risk." 21 and you're saying the mesh is going to Talking about dyspareunia. 22 increase this risk as compared to the 22 23 Why intuitively would you reason 23 native tissue repair, which is also a 24 that the mesh procedures would increase 24 foreign body implanted transvaginally. Page 91 Page 93 dyspareunia? 1 I'm just trying to understand 1 2 'Cause I'm putting in a foreign 2 why intuitively you would reason that the 3 3 body into the anterior vaginal wall, and mesh is going to increase that risk? 4 the foreign body, any time we do anything 4 So, some people may think that, 5 extra, there may be an increased risk for 5 and when we started putting in meshes we 6 developing complications. 6 actually counseled people that we may have 7 However, the data does not 7 a higher dyspareunia rate with 8 transvaginal mesh. However, once again, 8 substantiate that there's an increased 9 9 complication of dyspareunia with the data does not support there's an 10 transvaginal mesh. 10 increased rate of dyspareunia with transvaginal mesh as compared to native 11 And I think the Cochrane review 11 also comments on dyspareunia, and the tissue in multiple studies. 12 12 13 Cochrane review on page 17 going to 18: 13 Q. I'm trying to figure out why you "There was no evidence of a difference wrote this in your report. 14 14 Why would you reason that the between the groups in the rate of de novo 15 15 dyspareunia." 16 16 transvaginal mesh increases the risk of 17 O. And my question is why in your 17 dyspareunia as compared to native tissue report do you state that intuitively the 18 18 repair? 19 transvaginal mesh may increase the risk of 19 A. I didn't say it increases the dyspareunia? risk of dyspareunia. I said that you may 20 20 MR. ROSENBLATT: Object to form; 21 21 think it increases the risk of dyspareunia, but the literature has proven 22 asked and answered. 22 that it doesn't increase the risk. 23 A. Once again, intuitively, if 23 24 we're putting in a foreign body, if we're 24 So you don't reason that the

Page 94 Page 96 1 transvaginal mesh procedure would increase 1 transvaginal mesh for prolapse repair? 2 the risk? 2 A. My answer is going to be it's 3 3 Α. The data does not support that similar to native tissue repairs. transvaginal mesh increases the risk of 4 4 Q. And that's based upon just 5 dyspareunia. 5 discussing a lot of findings with no 6 6 statistical analysis; is that correct? Doctor, do vou have an estimate 7 as to what you, based on your review of 7 MR. ROSENBLATT: Object to form. the literature and clinical experience, as 8 8 He has an entire report here, so he's 9 to what the de novo dyspareunia rate is 9 not going to limit his answer to the 10 after transvaginal mesh is implanted for 10 question. BY MR. BENTLEY: 11 prolapse? 11 12 That's not a number that I have 12 You can answer, please. A. O. off the top of my head, but it's something So, what's the question again? 13 13 Α. Other than just citing a bunch 14 that I included in my report. So let's --14 we're talking about transvaginal mesh or of studies and then coming up with some 15 15 16 we're talking about abdominal mesh now? 16 estimate, I'm trying to figure out what Prolift and Gynemesh PS methodology you employed to get to this 17 17 18 implanted transvaginally. 18 estimate? 19 A. Sure, let's go to that. 19 A. So, this is my what I used and then I'm going to go to the 3systemic 20 (Pause.) 20 21 A. So, different studies have 21 reviews that show that there's no 22 reported different numbers. Native tissue difference in dyspareunia rates for native 22 23 repair by Abramov in 2005 showed an 23 tissue repairs and transvaginal mesh 24 increase in dyspareunia from increase from 24 repairs. Page 95 Page 97 8 percent to 17 percent. 1 So, ultimately you're going to 1 2 Let's go to transvaginal mesh. 2 be saying that the rate is whatever's in 3 3 (Pause.) the systematic review? 4 4 A. I know Nieminen actually showed MR. ROSENBLATT: Object to form. 5 5 a dyspareunia rate lower in the mesh BY MR. BENTLEY: 6 group. Native tissue had a 13 percent 6 Is that correct? Q. 7 reported evidence of vagina too tight and 7 I am going to say the rate is 8 percent in the mesh group. 8 8 going to be a composite of the systematic 9 9 Carey in 2009 did a 12-month reviews. 10 follow-up of dyspareunia, showed 16.7 10 And what's the composite rate 11 percent of sexually active in women in the 11 going to be that you're going to testify mesh group and 50.2 percent in the no mesh 12 12 to to the jury? 13 group developed dyspareunia. So we're 13 A. I'm going to testify, like I going to see about a 15 percent, once said, it's out there and I will -- if you 14 14 again gross number, of dyspareunia rate 15 are going to pin me down that I have to 15 16 after our surgical procedures. 16 answer a number, which I got to tell you right now I'm not comfortable with, it's 17 So, I'm trying to figure out 17 what you intend to testify as to these going to be somewhere in the 15 percent 18 18 complication rates. range, 10 to 15 percent range. 19 19 So, other than just reciting So, if a study found de novo 20 20 findings from four or five different dyspareunia after mesh repair higher than 21 21 22 studies, do you have any type of number 22 the 10 to 15 percent range, would that that you're going to tell the jury as to 23 23 cause you concern? 24 what the de novo dyspareunia rate is after 24 MR. ROSENBLATT: Object to form.

			1	
		Page 98		Page 100
1	 A. I'm sure we're going to find 		1	out of a hat, and that's what I did.
2	studies that are higher and we're going to		2	Q. I'm not asking you to pick a
3	find studies that are lower.		3	number out of a hat. I'm trying to figure
4	Q. And so you just picked the		4	out what you're going to tell the jury is
5	middle ground, or how did you reach that		5	the actual rate of dyspareunia after
6	10 to 15 percent range?		6	transvaginal mesh.
7	A. So, I'm trying to pick a middle		7	MR. ROSENBLATT: Object to form;
8	number, yeah.		8	asked and answered. I think he's told
9	I told you I wasn't comfortable		9	you it's going to be similar, but that
10	with giving you a number.		10	an average would be 10 to 15 percent
11	(Exhibit Winkler 10, Dietz		11	or will be some studies that are
12	article, was marked for		12	higher and some that are lower.
13	identification, as of this date.)		13	BY MR. BENTLEY:
14	BY MR. BENTLEY:		14	Q. So, what methodological analysis
15	Q. Doctor, I'm handing you what's		15	are you doing on the statistics to reach a
16	been marked as Exhibit 10. This is a		16	10 to 15 percent number?
17	study by Viviane Dietz and Christopher		17	A. I'm not. You're just asking me
18	Maher.		18	right now for a number to give you a
19	Do you see that?		19	number and you won't let me go on without
20	A. Yes, I do.		20	giving you a number. So I have to give
21	Q. And this is actually the same		21	you something.
22	Christopher Maher that is the lead author		22	Q. Well, your report you cite a lot
23	on the 2016 Cochrane.		23	of studies; is that correct?
24	Do you see that?		24	A. Right. So you can't that's
				3 7
		Page 99		Page 101
1	A. Yes, I do.		1	why I'm saying I can't be pinned down to a
2	Q. And this study is titled "Pelvic		2	number.
3	organ prolapse and sexual function."		3	Q. And you provided a large number
4	Is that correct?		4	of different findings; is that correct?
5	A. Yes, it is.		5	A. Yes, the numbers depend on your
6	Q. It was published in 2013 in the		6	patient population. The numbers depend on
7	International Urogynecological Journal,		7	your there's a lot of variables that go
8	correct?		8	into sexual dysfunction or pain with
9	A. Correct.		9	intercourse, and what I'm prepared to
10	MR. ROSENBLATT: It's reference		10	testify is that, and I will tell the jury
11	number 30 in his report.		11	that I it's very hard to come down to
12	MR. BENTLEY: What page is it?		12	an exact number of what patients are going
13	MR. ROSENBLATT: Page 29.		13	to get dyspareunia and pelvic pain with
14	THE WITNESS: I have it on page		14	each particular type of surgery. I wish I
15	21.		15	knew that. Then I can
16	MS. THOMPSON: It's 21 and 29		16	Q. So you're not going to
17	and 30.		17	A. It's a range.
18	BY MR. BENTLEY:		18	Q provide a complication rate
19	Q. So, I believe you just testified		19	for dyspareunia, is that your testimony?
	that the true range that you believe for		20	MR. ROSENBLATT: Object to form.
			21	If he's asked about a particular
20	<u> </u>		Z 1	II HE 3 d3NEU dDOUL a DalHCDiai
20 21	de novo dyspareunia after transvaginal			·
20 21 22	de novo dyspareunia after transvaginal mesh repair for prolapse is 10 to 15		22	study, then he's going to comment on
20 21	de novo dyspareunia after transvaginal			·

	Page 10	2	Page 104
1	entirely capable of reading a study.	1	you have an objection to form, I
2	I'm trying to figure out what	2	appreciate that.
3	expert analysis he's going to bring to	3	BY MR. BENTLEY:
4	the jury.	4	Q. Doctor, do you intend to offer
5	MR. ROSENBLATT: The jury can	5	an opinion at trial as to what the true
6	read a study all by themselves?	6	complication rate is for de novo
7	MR. BENTLEY: Well, I mean, if	7	dyspareunia after a native tissue repair?
8	you're just going to regurgitate	8	A. In the literature, if I didn't
9	findings, that's entirely not an	9	do the full systemic review and go through
10	expert analysis. You know that.	10	every single number that I have here, I
11	MR. ROSENBLATT: No, he's	11	would probably say that there is somewhere
12	providing his opinions based on all of	12	in the range of a 10 to 15 percent rate.
13	the studies	13	In my hands, do I believe that
14	MR. BENTLEY: I'm trying to	14	it is lower? Yes, I do. However, I have
15	figure out what his opinion is.	15	not done like a systematic review, but I
16	MR. ROSENBLATT: I know. And	16	have followed up on my patients and
17	I'm not trying to be disruptive. I'm	17	followed my native tissue repair patients,
18	just saying he has cited studies that	18	and I try to pick the appropriate surgery
19	cite specific rates, but you're not	19	with the patient to try to minimize some
20	asking him what is that range that's	20	of these risks of native tissue
21	reported in the studies. You're just	21	
22		22	dyspareunia rates.
	asking him BY MR. BENTLEY:		Q. Okay. And so it's your estimate
23		23	and your opinion that you intend to
24	Q. I'm saying based upon your	24	testify to that the range is approximately
	Page 10	3	Page 105
1	review of the literature as cited in the	1	10 to 15 percent for native tissue repair,
2	report, what is the true range of de novo	2	correct?
3	dyspareunia that you intend to testify to	3	A. Yes. And that also depends on
4	at trial?	4	what kind of repair that you're doing. If
	ac chair		Wilde Mila of repair clack you're doing. 2.
l 5	A Once again I intend to testify	5	you're doing a posterior repair if you're
5 6	A. Once again, I intend to testify that there's no difference in rates for	5 6	you're doing a posterior repair, if you're
6	that there's no difference in rates for	6	doing an anterior repair, but if we're
6 7	that there's no difference in rates for native tissue versus transvaginal mesh.	6 7	doing an anterior repair, but if we're going to lump everything together, I think
6 7 8	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of	6 7 8	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number.
6 7 8 9	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number.	6 7 8 9	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can
6 7 8 9 10	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break	6 7 8 9 10	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think
6 7 8 9 10 11	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break that down.	6 7 8 9 10 11	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific
6 7 8 9 10 11 12	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break that down. You don't have an opinion as to	6 7 8 9 10 11 12	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific number. But if you're going to ask
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6 7 8 9 10 11 12 13 14	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break that down. You don't have an opinion as to the true rate of native tissue repair for de novo dyspareunia; is that correct?	6 7 8 9 10 11 12 13 14	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific number. But if you're going to ask him MR. BENTLEY: Well, if we're
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6 7 8 9 10 11 12 13 14 15 16 17	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break that down. You don't have an opinion as to the true rate of native tissue repair for de novo dyspareunia; is that correct? MR. ROSENBLATT: Object to form; mischaracterization. To the extent he's relying on	6 7 8 9 10 11 12 13 14 15 16 17	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific number. But if you're going to ask him MR. BENTLEY: Well, if we're just going to say it's about the same as something else, I'm entitled to know what he's comparing it to and how
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break that down. You don't have an opinion as to the true rate of native tissue repair for de novo dyspareunia; is that correct? MR. ROSENBLATT: Object to form; mischaracterization. To the extent he's relying on particular studies, he will discuss those opinions, but to the extent you're asking him to pin it down to a specific number, he's saying that's difficult to do.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific number. But if you're going to ask him MR. BENTLEY: Well, if we're just going to say it's about the same as something else, I'm entitled to know what he's comparing it to and how he reached that. We haven't figured out any methodology for doing any type of combination of these studies. A. So, I look at the Cochrane review, its the Schimpf review, the
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	that there's no difference in rates for native tissue versus transvaginal mesh. I'm not so sure we know the true rates of either to an exact number. Q. So you don't know let's break that down. You don't have an opinion as to the true rate of native tissue repair for de novo dyspareunia; is that correct? MR. ROSENBLATT: Object to form; mischaracterization. To the extent he's relying on particular studies, he will discuss those opinions, but to the extent you're asking him to pin it down to a specific number, he's saying that's	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	doing an anterior repair, but if we're going to lump everything together, I think we can come to that number. MR. ROSENBLATT: Maybe I can help streamline this. I don't think he's offered in his report a specific number. But if you're going to ask him MR. BENTLEY: Well, if we're just going to say it's about the same as something else, I'm entitled to know what he's comparing it to and how he reached that. We haven't figured out any methodology for doing any type of combination of these studies. A. So, I look at the Cochrane

		T	
	Page 1	6	Page 108
1	Q. Doctor, what's your opinion as	1	exactly. That would make all of our lives
2	to the complication rate of chronic pain	2	easier, but it's a variable rate and takes
3	after a native tissue repair done	3	
4	transvaginally for prolapse?	4	·
5	A. The chronic pelvic pain rate,	5	you're asking for.
6	are you including dyspareunia in that or	6	Q. Maybe let's do it this
7	not including dyspareunia in that?	7	direction.
8	Q. You can tell me both, if that's	8	Which studies you have 40
9	easier.	9	pages of studies in here. Which studies
			• •
10		10	•
11	just exclude dyspareunia. Let's assume	11	, 3
12	they're not.	12	<u> </u>
13	I also think it's low. I think	13	
14	the chronic pain rate from a native tissue	14	,
15	repair depend is going to be in the low	15	•
16	numbers, the low single digit numbers.	16	
17	Q. And then your opinion is the	17	go back here.
18	transvaginal mesh used to treat prolapse	18	(Pause.)
19	is going to be approximately the same as	19	There's the Withagen study, the
20	native tissue repair; is that correct?	20	Altman study.
21	A. That's what's in the studies.	21	Q. Let's do those one by one.
22	And on chronic pain it's very limited	22	•
23	data, if I'm correct.	23	5 ,
24	Q. So, when you say a very low	24	,
	to con interview out a very ion		
	Page 1	7	Page 109
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1 2	number, what numerically are we talking	1	Q. And is the Altman review a
2	number, what numerically are we talking about in a range?	1 2	Q. And is the Altman review a systematic meta-analysis?
2	number, what numerically are we talking about in a range? A. Range anywhere between, if I	1 2 3	Q. And is the Altman review a systematic meta-analysis?A. No, it's not.
2 3 4	number, what numerically are we talking about in a range? A. Range anywhere between, if I have to pick a number, once again which	1 2 3 4	Q. And is the Altman review a systematic meta-analysis?A. No, it's not.Q. What other studies did you find
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2 3 4 5 6 7 8	number, what numerically are we talking about in a range? A. Range anywhere between, if I have to pick a number, once again which I Q. Based upon your review of the literature and your systematic reviews. A. So let's go through the numbers here. I wasn't prepared to give a number	1 2 3 4 5 6 7 8	Q. And is the Altman review a systematic meta-analysis? A. No, it's not. Q. What other studies did you find most compelling? A. So, the only systemic review that I included in my report was the Cochrane review. Q. And the Cochrane review, as
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2 3 4 5 6 7 8 9 10 11 12 13 14	number, what numerically are we talking about in a range? A. Range anywhere between, if I have to pick a number, once again which I Q. Based upon your review of the literature and your systematic reviews. A. So let's go through the numbers here. I wasn't prepared to give a number like that. Q. Well, let's be clear. You're establishing that Prolift	1 2 3 4 5 6 7 8 9 10 11 12 13	Q. And is the Altman review a systematic meta-analysis? A. No, it's not. Q. What other studies did you find most compelling? A. So, the only systemic review that I included in my report was the Cochrane review. Q. And the Cochrane review, as we've seen, the authors concluded that the risk-benefit profile doesn't make sense for a primary treatment surgery for prolapse, right? MR. ROSENBLATT: Object to form.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	number, what numerically are we talking about in a range? A. Range anywhere between, if I have to pick a number, once again which I Q. Based upon your review of the literature and your systematic reviews. A. So let's go through the numbers here. I wasn't prepared to give a number like that. Q. Well, let's be clear. You're establishing that Prolift and Gynemesh PS are safe because you think they're safe as native tissue repair; is that fair? A. Based on the literature I reviewed, there's no increase in rate of dyspareunia rates and chronic pain rates. Q. Right. So saying there's no increase in one rate as compared to the	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And is the Altman review a systematic meta-analysis? A. No, it's not. Q. What other studies did you find most compelling? A. So, the only systemic review that I included in my report was the Cochrane review. Q. And the Cochrane review, as we've seen, the authors concluded that the risk-benefit profile doesn't make sense for a primary treatment surgery for prolapse, right? MR. ROSENBLATT: Object to form. A. But they also showed that there was no difference in dyspareunia and pelvic pain. Q. Right. A. Associated with the two repairs. Q. So your conclusions are just
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	number, what numerically are we talking about in a range? A. Range anywhere between, if I have to pick a number, once again which I Q. Based upon your review of the literature and your systematic reviews. A. So let's go through the numbers here. I wasn't prepared to give a number like that. Q. Well, let's be clear. You're establishing that Prolift and Gynemesh PS are safe because you think they're safe as native tissue repair; is that fair? A. Based on the literature I reviewed, there's no increase in rate of dyspareunia rates and chronic pain rates. Q. Right. So saying there's no increase in one rate as compared to the other one, I have no idea what rates you're comparing. It's not I'm not	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And is the Altman review a systematic meta-analysis? A. No, it's not. Q. What other studies did you find most compelling? A. So, the only systemic review that I included in my report was the Cochrane review. Q. And the Cochrane review, as we've seen, the authors concluded that the risk-benefit profile doesn't make sense for a primary treatment surgery for prolapse, right? MR. ROSENBLATT: Object to form. A. But they also showed that there was no difference in dyspareunia and pelvic pain. Q. Right. A. Associated with the two repairs. Q. So your conclusions are just different? A. No, we're concluding the same
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Page 110 Page 112 1 So you do agree that the 1 5 percent of my patients are choosing 2 risk-benefit profile for Prolift and 2 that. 3 Gynemesh PS that it doesn't make sense as 3 I will say most patients at this 4 4 a primary surgery for general population point in time are scared away from 5 with the exception of some -- the 5 transvaginal mesh and won't even entertain 6 6 exception of the possibility that some the thought of transvaginal mesh because 7 high risk patients it might make sense 7 of the advertisements and ongoing 8 for. Do you agree with that? 8 litigation that's out there, and every 9 9 single patient almost brings it up. A. In my opinion, transvaginal mesh is not the procedure that patients will Well, how about what percent of 10 10 choose based on their goals. your patients that you treat for prolapse 11 11 How's that? do you think Prolift and Gynemesh PS is 12 12 Q. Would you agree with -appropriate for? 13 13 MR. ROSENBLATT: Object to form. 14 14 A. I think it could be an Could you read back that answer? 15 15 appropriate procedure for a larger (The requested portion of the percentage as long as they understand the 16 16 record was read by the Court Reporter.) risk and the benefits. But we're not even 17 17 18 That patients may choose. 18 getting there at this point in time, and I Α. So the patients are choosing not understand that, and I never push a 19 19 Q. to use a transvaginal mesh as the primary 20 20 patient into a procedure, especially if they don't want it. That's not the right 21 treatment for their goals? 21 They may choose that, yes. 22 thing to do. But I think that the 22 23 So, if I'm putting a synthetic 23 conversation is even stopping because of 24 in and a patient wants a synthetic 24 what's going on. Page 111 Page 113 procedure, they may choose to go with an 1 Doctor, you cite to a number of 1 2 abdominal sacrocolpopexy as opposed to a 2 transvaginal mesh studies in your report, transvaginal mesh, understanding that the 3 3 and then you cite to some studies and you 4 sacrocolpopexy has increased risks of it 4 provide findings specifically for Prolift 5 being an intra-abdominal procedure, but 5 and Gynemesh PS. 6 abdominal sacrocolpopexy has a lower risk 6 My question is are you relying 7 profile likely for dyspareunia. 7 upon other mesh products to reach your 8 Q. Let's go at this way. 8 opinions regarding the safety and efficacy 9 9 of these Ethicon products? Today you do approximately -today for approximately 5 percent of the 10 10 A. Other mesh products will be in 11 patients you treat for prolapse, for 5 11 there, but the -- the predominance of data percent of them you're doing a is on Ethicon products. 12 12 transvaginal mesh repair? (Exhibit Winkler 11, Altman 13 13 Yeah, at the most, yeah. article, was marked for 14 14 And that's consistent with your 15 15 identification, as of this date.) 16 understanding of the risk-benefit profile 16 BY MR. BENTLEY: of these devices; is that fair? 17 17 Doctor, I'm handing you what's For the patients that I'm being marked as Exhibit 11, which is the 18 18 Altman study we discussed. 19 treating, that's fair. 19 20 So maybe the mesh repair 20 Α. Yes. 21 transvaginally is appropriate in maybe 5 21 Q. And you're familiar with the percent of the patients consistent with 22 22 Altman study? 23 your clinical practice? 23 Yes. Α. 24 That I didn't say. That's maybe 24 And the Altman study was Q.

Page 114 Page 116 1 published in the New England Journal of 1 A. I don't think the cystoscopy one 2 Medicine; is that correct? 2 is. I pretty much do intraoperative 3 3 cystoscopy on every patient. That's correct. Α. That's a reputable publication, 4 4 Q. You do one cystoscopy rather Q. 5 right? 5 than multiple, right? 6 6 Not necessarily, in my patients. Α. Yes. 7 And the article is titled 7 If there was more frequent Q. 8 8 cystoscopy, at least these authors "Anterior Colporrhaphy Versus Transvaginal 9 Mesh For Pelvic Organ Prolapse." 9 indicate that that's a increased adverse 10 Is that correct? 10 event associated with mesh-based repair; 11 A. Yes. 11 is that correct? 12 And on the first page in the 12 They're adding it, but in my O. Α. 13 abstract, you can see the author's 13 uterosacral suspensions, my native tissue conclusions: "As compared with anterior repairs, we actually do two cystoscopies 14 14 colporrhaphy, use of a standardized trocar 15 in those procedures. 15 quided mesh kit for cystocele repair." O. And these authors note that: 16 16 And that's the Prolift kit, "Compared to native tissue repair, these 17 17 18 18 authors note that compared to traditional right? colporrhaphy that the mesh group had more 19 Correct. 19 Α. 20 0. And that kit resulted in a 20 need for intraoperative cystoscopy at p-equals .006." 21 higher short-term rate of successful 21 22 treatment, but also in higher rates of 22 Do you see that? 23 surgical complications and postoperative 23 A. I see that. 24 adverse events. 24 And that's highly significant, Page 115 Page 117 Is that correct? 1 right? 1 2 2 A. I see that's significant. I Α. That's what it states. 3 3 And on page 1833 of the study, don't know if these doctors, if they did 4 the authors discuss those adverse events. 4 any such anterior colporrhaphy if they 5 Do you see the "Adverse Events" 5 would cystoscope these patients. I would 6 6 because there's data out there to support, section? 7 7 to show that when you do an anterior A. Yes. 8 repair, you can get cubital kinking from a 8 And they note that the mesh 9 native tissue repair. 9 repair group had a significantly longer mean duration of surgery. 10 And the authors continue: "More 10 Q. 11 Do you see that? 11 bladder perforations occurred in the mesh repair group than the colporrhaphy group." 12 Yes, I do. 12 Α. Do you see that? 13 The mesh repair group had a 13 greater mean interoperative blood loss. Yes, I do. 14 14 15 Do you see that? 15 And the next sentence, or a 16 A. Yes. 16 little bit farther down the authors note: "The inquinal pain and bladder emptying 17 And the mesh group had more 17 O. difficulties during hospital stay were frequent need for interoperative 18 18 more common after mesh repair." 19 cystoscopy. 19 Do you see that also? 20 Do you see that? 20 21 Yes. I do. 21 Yes, I do. Α. And those are all significant 22 22 And these authors were O. complications for the patient; is that 23 23 specifically looking at the Prolift kit; 24 24 is that correct? fair?

Page 118 Page 120 the bottom right, you see: "The one year 1 They're doing more surgery here. 1 2 I'm not surprised to see some more 2 assessment symptoms of stress urinary 3 3 adverse. incontinence were significantly more 4 4 bothersome in the mesh repair group than Q. This study is specifically 5 looking at the Gynecare Prolift kit? 5 the colporrhaphy group." 6 6 I understand, but when vou're A. I'm aware of that. 7 putting in the mesh, you're still doing 7 Can you just show me the number 8 more surgery than you would be doing at a 8 we're talking about? 9 Q. It's on the -- it's p equals traditional anterior colporrhaphy. 9 0.02. So statistically --10 So these authors looked at 10 implanting the Gynecare Prolift kit and A. You're talking about the UDIS 11 11 found increases in all of these adverse 12 12 subscale? 13 events; is that correct? I'm on the text on the far right 13 Q. 14 A. That's correct. I'm not 14 column. 15 surprised to see that. 15 The authors in Altman note that 16 16 And if you look at the there's increased stress urinary difference in greater mean intraoperative incontinence that's bothersome in the mesh 17 17 18 blood loss, 84 to 35, we're talking about 18 group compared to the anterior not even two ounces of blood. 19 19 colporrhaphy. 20 So, these authors conclude that 20 Riaht? 21 there's a greater risk of adverse events 21 A. Yes. 22 with the Prolift kit. 22 And the authors continue on the 23 In your report, you discuss the 23 next page that: "New stress urinary 24 Altman study on page 29 and on page 32. 24 incontinence occurred in 6.2 percent of Page 119 Page 121 1 A. Okay. 1 the patients in the colporrhaphy group 2 versus 12.3 percent in the mesh repair 2 You don't appear to address 3 group, statistically significant." 3 these authors' conclusions. 4 4 Do you see that? As you sit here today, do you 5 5 have a criticism of the authors' Yes, I do. 6 conclusions in the Altman study? 6 And is that consistent with your 7 A. I don't have a criticism for 7 clinical practice that stress urinary 8 incontinence is more common with mesh as 8 them putting it in. 9 9 Clinically significant, once with colporrhaphy? 10 again, the mean intraoperative blood loss 10 That's consistent with the data. Α. 11 when we're going from a little over an And on that column on the right 11 ounce to a little less than three ounces on that same page, the authors note that: 12 12 "Pain during sexual intercourse was 13 is not clinically significant. 13 14 The more frequent need for reported to occur usually or always by 2 14 intraoperative cystoscopy, once again not percent of the women after colporrhaphy 15 15 16 clinically significant. 16 and by 7.3 percent after transvaginal mesh 17 And the duration of the surgery, 17 surgery." I would expect it to last longer and Do you see that? 18 18 19 that's what we would discuss with the 19 A. I see that. And the p-value's 20 patient because we are doing more surgery 20 not significant. when we are putting in a transvaginal mesh 21 21 So, because the p-value's not 22 than doing a simple anterior colporrhaphy. 22 significant, you would discount the Altman On page 1831 in Altman, the 23 23 finding? 24 authors note that at the one year -- on 24 A. I wouldn't discount it, but it's

		T		
	Page 122		P	Page 124
1	not a significant finding.	1	comment on any of that or just continue	
2	Q. Is that finding of increased	2	reading?	
3	dyspareunia consistent with your clinical	3	MR. ROSENBLATT: You can take	
4	practice?	4	your time and read the entire article,	
5	A. This is one study	5	if you need to.	
6	MR. ROSENBLATT: Object to form.	6	THE WITNESS: Okay.	
7	A showing that.	7	(Perusing document.)	
8	And in my clinical practice, the	8	BY MR. BENTLEY:	
9	dyspareunia rate is equivalent to the	9	Q. So, in your report on page 29	
10	nature tissue repair native tissue	10	you discuss	
11	rate.	11	A. I'm not finished reading it, I	
12	THE WITNESS: Can we go off the	12	apologize.	
13	record?	13	MR. BENTLEY: Well, if you want	
14	(Discussion held off the record.)	14	to go off the record, you can read	
15	BY MR. BENTLEY:	15	literature.	
16	Q. Doctor, are you familiar with	16	THE WITNESS: Sure.	
17	studies by Milani?	17	(Perusing document.)	
18	A. Who?	18	Okay.	
19	Q. Milani, M-I-L-A-N-I.	19	BY MR. BENTLEY:	
20	A. Can you show me that study?	20	Q. Doctor, in your report, you note	
21	(Exhibit Winkler 12, Damoiseaux	21	that this study by Damoiseaux in 2015	
22	abstract, was marked for	22	found no differences in overall rates of	
23	identification, as of this date.)	23	dyspareunia between Prolift and the	
24	dentification, as or this detery	24	traditional repair; is that correct?	
		- '	additional repair, to that correct	
	Page 123		F	Page 125
1	Page 123 BY MR. BENTLEY:	1	A. Yes.	Page 125
1 2	BY MR. BENTLEY:	1 2	A. Yes.	Page 125
2	BY MR. BENTLEY:		A. Yes. Q. Are you with me on page 29 of	Page 125
	BY MR. BENTLEY: Q. Doctor, I'm handing you what's	2	A. Yes. Q. Are you with me on page 29 of your report?	Page 125
2 3 4	BY MR. BENTLEY: Q. Doctor, I'm handing you what's being marked as Exhibit 12.	2	A. Yes. Q. Are you with me on page 29 of	Page 125
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Page 126 Page 128 1 goals and objectives for the surgical 1 little farther up in that paragraph, is 2 procedure. 2 that the mesh exposure rate was extremely 3 3 So you cite their finding about hiah. 4 4 dyspareunia rates, but you don't address Do you see that? 5 their conclusion in your report; is that 5 A. Yes, I do, and I was looking in 6 6 the study to see what their exposure rate correct? 7 My understanding is this 7 Α. was. 8 litigation is not about the efficacy of a 8 My copy is a little different, 9 transvaginal mesh procedure, but it is 9 but in mine there's a chart 40 percent regarding the complications of a 10 10 exposure. transvaginal mesh procedure. 11 11 Is that consistent with the copy Is that not accurate? 12 12 you have? 13 That wasn't my question. Right. And you had a 7 percent 13 You provide -- you cite a exposure rate in the conventional group, 14 14 finding from this study in your report, which we have been talking about as -- you 15 15 but you don't address the authors' 16 know, doesn't really happen. So how did 16 they get their 7 percent there? ultimate conclusion recommending 17 17 18 alternative non-mesh surgical procedures; 18 So, my first question is you don't address a 40 percent exposure rate 19 is that correct? 19 20 Once again, alternative non-mesh 20 in your report, right? 21 procedures should be discussed with each 21 A. Once again, we were not 22 individual patient, and making a blanket discussing that in this particular 22 23 statement that you should do other, and 23 subsection. 24 they don't say you should do other, that 24 These were patients who had Page 127 Page 129 you should consider others, then that's 1 anterior and posterior meshes and we prior 1 2 what you need to discuss with your 2 discussed that I think if someone's going 3 3 patients, and they don't say you shouldn't to have an anterior and posterior mesh 4 do the surgery. You should seriously 4 that you may see up to a 24 percent 5 consider it. And I agree with that, they 5 exposure rate. So I don't know if 24 and 6 can consider it. You need to consider all 6 40 percent is going to be significant. 7 the risks and the benefits of a surgical 7 Q. In your report, Doctor, you cite 8 8 procedure. the study, right? 9 9 A. Yes, I do. So you should -- let me get it Q. And you state: "7 year 10 10 clear. 11 You agree with the authors' 11 follow-up data was presented by Damoiseaux ultimate conclusion that you should 2011 in abstract form and reported 10 12 12 percent de novo dyspareunia rate in the 13 seriously consider non-mesh treatments? 13 No, I agree with the author that mesh group and 12 percent in the no mesh 14 14 15 you should seriously discuss non-mesh and group." 15 16 mesh surgical treatments with your 16 Correct? 17 patients. 17 A. Correct, that's what's written I agree -- I agree with the 18 18 in my report. statement to start off, not to end. You 19 19 Q. In the next sentence you state: should have this discussion with your "There is no difference in overall rates 20 20 21 patients before you do the surgery, not 21 of dyspareunia as well between the two 22 22 groups." afterwards. 23 One of the other conclusions at 23 Correct? 24 the seven-year follow-up, if you look a 24 There is no statistically

Page 130 Page 132 significant difference, and if you look at 1 1 know, and this is only in abstract form, 2 the paperwork from 2015, the p-value for 2 how many of these were symptomatic, how 3 dyspareunia and the p-value for de novo 3 many of these were not symptomatic, and 4 4 dyspareunia is nonsignificant. what was the follow-up. Why didn't they 5 So in your report, you discuss 5 include the -- if there was a significant 6 6 the dyspareunia rate, but you don't number in patients going back to the 7 discuss the exposure rate and you don't 7 operating room, they would have that, why 8 discuss the authors' ultimate conclusion, 8 wouldn't they put that in? 9 9 MR. ROSENBLATT: Greg, how much correct? 10 Α. Once again, in this subsection, 10 more do you have? that was not called for here and that is MR. BENTLEY: Do you want to 11 11 12 not in my report. 12 take a break? Because it didn't agree with MR. ROSENBLATT: I think it 13 13 14 your conclusion there? 14 would be good. 15 MR. ROSENBLATT: Objection. 15 MR. BENTLEY: I'm fine with 16 16 that. Let's do that. 17 17 MR. ROSENBLATT: Object to form. (Recess taken from 6:27 p.m. to 18 My conclusion was, and they 18 6:33 p.m.) A. concluded it themselves as well, that BY MR. BENTLEY: 19 19 there's no -- in their conclusions, there 20 20 Doctor, one of the bases for 21 was no difference in pain or dyspareunia 21 your opinions today that Prolift and 22 between the two groups. I am quoting Gynemesh PS is save and effective is your 22 23 23 own personal clinical experience; is that that. 24 Q. That's one of their conclusions 24 fair? Page 131 Page 133 you cite in your report, right? 1 Α. That's fair. 1 2 And I've never denied that 2 And we discussed this a little Ο. 3 3 there's an exposure rate that can happen bit earlier today regarding TVT, but you 4 with meshes and you need to take that into 4 don't keep a case log for your prolapse 5 5 patients, do you? consideration. 6 Q. Nowhere else in your report do 6 No, I do not. Α. 7 you discuss their 40 percent finding of 7 And you don't have any exact exposure rate at 7-year follow-up. 8 numbers for how many of your patients that 8 9 And my question is why do you 9 you did a Prolift procedure with mesh 10 10 suffered complications, right? not discuss that? 11 It was not relevant to this 11 A. I don't, but I do have anecdotal Α. follow-up on patients who have 12 subsection. 12 13 You discuss exposure rates 13 transvaginal mesh, I asked to return elsewhere in your report, right? yearly to the office and I monitor them. 14 14 I discussed exposure rates 15 15 And then once again, if anybody else was 16 elsewhere in my reports and I go with the 16 removing any of the transvaginal meshes overall gestalt. I did not include this that I placed, as a general rule, they 17 17 in the exposure rate, that I am aware of. probably would tell me. There are 18 18 And the 40 percent exposure rate exposures that I went back on and had to 19 19 is well beyond any acceptable exposure revise. I'm not aware of any of my 20 20 rate you've testified to today, right? transvaginal mesh procedures where 21 21 22 This is higher than I would like 22 somebody went back in and had to remove Α. the entire piece of mesh. 23 to see, but this is one study only. 23 24 And once again, I'd like to 24 So you don't know what

Page 134 Page 136 1 percentage of your patients had a 1 right? 2 complication after Prolift, right? 2 A. It's the follow-up that I do 3 3 So, my exposure rate is with them yearly, yes. 4 consistent with the literature. My 4 Q. And we've discussed you don't 5 reoperation rate as a whole is lower than, 5 actually have numbers for that, right? 6 6 I think, the literature because these A. Correct. And then another basis is your 7 asymptomatic mesh exposures were not 7 Q. taking patients back to the operating room 8 8 literature review, right? 9 9 for as much these days. Correct. Α. What's your exposure rate? 10 10 And then the third basis that O. Ο. I would -- around 10 to 12 11 11 you just told me is your 522 study that 12 percent for each compartment that mesh is 12 you started regarding Elevate; is that 13 placed in. 13 correct? 14 Q. How are you reaching a 10 to 12 14 A. Correct. 15 exposure rate, how do you have that 15 Q. And that study wasn't finished 16 estimate if you don't keep track of the 16 either, right? No, it was not. Although no number of --17 17 18 So, I'm basing it just on 18 one's denying that mesh exposures happen A. patients that I've seen back, as well as 19 19 with any times we put in meshes. 20 the average numbers in the literature, but 20 Q. I'm just trying to figure out 21 I'm basing it on the numbers of patients 21 what your personal experience with 22 that I've seen. exposure rates would be because that's one 22 23 We were participating in the 522 23 of the bases for your opinions, right? 24 study for Elevate. Unfortunately, that 24 But we don't have a number? Page 137 Page 135 was stopped because Astora went out of --1 We don't have an exact number. 1 2 had closed down. 2 We need to go by the literature's number 3 and my clinical experience. 3 Q. Is that your own opinion, or was 4 this told to you that the 522 order was 4 What's the robotic assisted 5 stopped because Astora went out of 5 sacrocolpopexy exposure rate that you're 6 business? 6 aware of or that's your opinion? 7 7 Well, we do the procedure with a I mean, we participated in the Α. 8 super -- or, I do the procedure most 8 study. They said we're going out of 9 business, we're not funding the study 9 commonly with a supracervical hysterectomy 10 10 in order to avoid any incisions on the anymore. 11 O. If Astoria was not, in fact, out 11 vagina. The rate reported in the of business and their stock price was literature for abdominal sacrocolpopexy 12 12 13 rising today, would that maybe change your 13 with polypropylene mesh is anywhere from opinion as to why the study was stopped? about a half percent to 3 percent, if I 14 14 remember correctly. That may be based on I don't think the study was 15 15 16 stopped for complications. I think the 16 a Schimpf -- is that on Schimpf from the study was stopped for business decisions, 17 17 meta-analysis? monetary decisions. THE WITNESS: Do we have that 18 18 19 I don't recall having to take 19 paper, Paul? Could we get that? 20 back any of my patients who received mesh 20 MR. ROSENBLATT: It's not in that study back to the operating room. 21 21 printed out. 22 All right. So, we have your 22 THE WITNESS: Okay. anecdotal recounts of your patients as one 23 23 BY MR. BENTLEY: 24 of the basis for your exposure rate, 24 Go ahead. Q.

Page 138 Page 140 A. And based on some older data 1 1 state that it's scarce; is that correct? 2 that actually I think is quoted in my 2 A. It's a low number with 3 3 report. Let's see if we can find that sacrocolpopexy. 4 Nygaard study with the polypropylene as 4 Q. I think on page 31 at the top 5 opposed to the graft material. 5 you state: "There's extremely limited 6 6 MR. ROSENBLATT: It's Tab 39, if data on the development of the available 7 7 of dyspareunia after sacrocolpopexy you wanted to see it. 8 8 THE WITNESS: Okay. Let's just attesting to the scarcity of it occurring." 9 9 see 39 here. 10 A. So, the most recent Cochrane 10 Do you see that? review reports a mesh exposure of 3 A. Right. And the recent Cochrane 11 11 percent. The erosion rate in the Nygaard review was unable to report on the rate of 12 12 paper included a bunch of patients who had de novo dyspareunia with an abdominal 13 13 woven polyester or Gore-Tex. 14 14 sacrocolpopexy. In 2008 Cundiff had a 5.1 So based upon de novo 15 15 Q. 16 erosion rate, but I'm going to the most 16 dyspareunia, abdominal sacrocolpopexy is common erosion rate in 2016 of only 3 safer for the patient such that they're 17 17 18 percent. And we try to reduce that rate 18 not at risk of developing dyspareunia de 19 by doing, if we're going to do it as a 19 novo? 20 primary repair, as a supracervical 20 MR. ROSENBLATT: Object to the 21 hysterectomy versus a total hysterectomy. 21 form. 22 So, it's your opinion that the 22 Well, safer -- dyspareunia is 23 sacrocolpopexy mesh exposure rate is 23 not a safety issue. Dyspareunia is a 24 approximately 3 percent? 24 quality of life issue. Page 139 Page 141 Α. Correct. 1 So, with respect to 1 2 And that's based upon your 2 sacrocolpopexy using mesh, there's a lower Q. 3 3 reliance on the 2016 Cochrane report that rate of de novo dyspareunia as compared to 4 we've reviewed; is that correct? 4 Prolift for women that are being treated 5 5 for prolapse; is that correct? Primarily. 6 THE WITNESS: Can we get the 6 A. There's a lower rate for 7 Schimpf one printed out? 7 sacrocolpopexy with trans -- as compared 8 8 MR. ROSENBLATT: I could pull it to transvaginal mesh, as well as native 9 9 up, but I can't print it out. tissue repairs. 10 Do you mind if I pull it up for 10 Doctor, what do you mean in your 11 11 report on page 33 when you state that: "A him? patient required wide mesh excision"? 12 MR. BENTLEY: That's fine. 12 What's the significance of describing it 13 MS. THOMPSON: We may have it. 13 THE WITNESS: You have the as a wide excision? 14 14 15 Schimpf paper, the 2016 meta-analysis. A. Where in my report is that? 15 16 BY MR. BENTLEY: 16 O. I'm at the top. 17 If you're citing to that and 17 Is there any significance to that's your basis for it, that's all I'm describing something as a wide excision? 18 18 A. I'm describing what they 19 trying to figure out. 19 Yeah, it's somewhere around the 20 20 described. A wider mesh incision is 21 3 percent. I think in the Schimpf paper 21 probably removing more mesh than just 22 it was lower, I just can't remember. 22 cutting out a small mesh exposure. I'd And de novo dyspareunia with have to look at that paper to get an 23 23 24 sacrocolpopexy, I think in your report you 24 exact -- an exact understanding of what

Page 142 Page 144 they meant. So why don't we pull out the to 30 percent? 1 1 2 Landsheere paper 2001. 2 A. Yeah, I recall. 3 Q. I'm just asking you if there's 3 And I'd like to get that study 4 any significance to describing it as a 4 out, if we can. Once again, I can't 5 wide excision. 5 remember things by heart. 6 6 A. Wider than it was more -- more Sure. 7 7 extensive of a dissection that was And you think it's Paraiso 2011 8 8 necessary than just a simple excision. on page 39 of your report? 9 9 Q. Doctor, I think we've talked A. No, that's not it. about it, but can you tell me again what 10 10 It's a Paraiso study on you intend to testify as to the rate of posterior repair comparing traditional 11 11 dyspareunia for native tissue repair colporrhaphy repair to -- to porcine, I 12 12 13 transvaginally? think, and to cite specific. 13 Q. So, I think I understand. 14 A. So, that's going to depend on 14 what's being performed at the transvaginal Your testimony is that posterior 15 15 repair has a higher rate of dyspareunia? repair. If we're doing a posterior 16 16 repair, there have been reports of up to 17 17 A. Yes. 18 30 percent dyspareunia rates, if we're 18 Okay. Q. just doing an apical suspension or if 19 19 Α. How's that? 20 we're just doing an anterior repair. So I 20 Q. And you think that's up to 30 would try to qualify what we're doing and 21 21 percent? 22 in the repair and testify that native 22 So, I said it's been reported up Α. 23 tissue repairs do have a dyspareunia rate 23 to 30 percent. I don't see it that high, 24 and it's variable depending on the 24 but it has been reported that high. Page 143 Page 145 procedures performed. 1 And as we've seen, there's a 1 2 Q. And what's your basis for 2 variation in rates reported in various 3 3 stating that it's up to 30 percent? studies, right, for various complications, 4 A. I think the Paraiso study showed 4 riaht? 5 that it was almost up to a 30 percent de 5 A. Agreed. 6 novo dyspareunia rate. 6 And is 30 percent your average Q. 7 7 number, or is that on the high end of --Let's see. 8 A. That would be on the high end. 8 (Perusing document.) 9 Do you know where that Paraiso 9 So what's actually the true rate 10 dyspareunia repair study is? 10 of dyspareunia you intend to --11 You discussed the Paraiso at the 11 It depends on the patient that bottom of page 27, it looks like. I'm operating on. It depends on the 12 12 procedures that I'm performing. And it 13 A. But that's a different study. 13 There's a Paraiso posterior depends on the situation that's going on, 14 14 if I'm doing abdominal sacrocolpopexy 15 repair study comparing -- it's a Paraiso 15 16 study of posterior repair. There was no 16 versus native tissue repair versus trans -- I don't think there was dyspareunia versus if the patient has 17 17 transvaginal mesh. I think it was site atrophy already, do they have a painful 18 18 intercourse already. It's so variable 19 specific versus porcine versus an anterior 19 it's hard to pin down to an exact number 20 study. 20 21 I'm trying to figure out what 21 of what the dyspareunia rate is going to 22 you intend to testify to as the 22 be, and that's why it's so hard in the literature because there's so many 23 dyspareunia rate for native tissue repair, 23 24 and I believe you testified that it's up 24 variables that go into dyspareunia, and as

Page 146 Page 148 1 time goes on, dyspareunia rates go up. 1 repair? 2 Q. I'm going to hand you what's 2 Α. So, Paraiso in 1996 reported a 3 being marked as Exhibit 13. 3 16 percent dyspareunia rate and -- after 4 4 sacrospinous suspension. (Exhibit Winkler 13, Lowman I'm trying to find -- okay. 5 article, was marked for 5 Weber et al. 2000 reported of a de novo 6 identification, as of this date.) 6 7 7 dyspareunia rate occurring in 26 percent BY MR. BENTLEY: 8 8 of women after posterior colporrhaphy. It's a study that is by Joye 9 Lowman entitled: "Does the Prolift system 9 Citation 54 in my report. So, is it your testimony that cause dyspareunia?" 10 10 Do you see that? you think that's the true rate of de novo 11 11 dyspareunia is figure for posterior 12 A. Yes. 12 13 And these authors were actually repair? 13 Q. trying to investigate this very question, 14 14 MR. ROSENBLATT: Object to form; 15 15 right? mischaracterization. 16 16 Α. Correct. A. I'm saying in that study, she And the conclusion they have is saw 26 percent rate of de novo dyspareunia 17 O. 17 18 that Prolift is associated with a 17 18 occurring with posterior repair. Q. Okay. So, let's be clear. 19 percent de novo dyspareunia. 19 20 Do you see that on top of the 20 In response to the Lowman study 21 first page? 21 that evaluates dyspareunia in Prolift, you just told me about a study from Weber from 22 Yeah. A. 22 23 Hold on. Where is Lowman in my 23 2000 that found 26 percent dyspareunia in 24 report? 24 posterior repair; is that correct? Page 147 Page 149 Q. 28. 1 A. I'm saying that posterior repair 1 may have a higher incidence of de novo 2 But is that the conclusion from 2 3 3 these authors? dyspareunia than anterior repair. 4 4 Q. And is the study that actually A. Hold on. I just want to find it 5 in my report, if that's okay. 5 looked at Prolift de novo dyspareunia 6 (Pause.) 6 limited to posterior repair? 7 Okay. Go ahead. 7 A. It's no. 8 8 O. And these authors that evaluated But what I'm saying is many of 9 9 dyspareunia with Prolift concluded there's these patients had a posterior mesh a 17 percent de novo dyspareunia rate, placed. So you need to compare those 10 10 11 correct? 11 patients and the dyspareunia rate, if you're saying things are higher or lower, 12 A. Correct. 12 13 And in my report it says, and I 13 to the posterior repair rates that we have was trying to find where it is: "As on native tissue. 14 14 stated prior, native tissue posterior 15 15 Let's try and compare apples to Q. 16 repair has significant risk of developing 16 apples. de novo dyspareunia. Therefore taking 17 17 You're citing a study Weber 2000 this in consideration, it seems that the that's specifically talking about 18 18 16.7 percent rate is consistent with the posterior, right? 19 19 native tissue studies." 20 20 That's correct. Α. 21 O. I didn't ask you about that. 21 0. Okav. 22 22 Α. And if we look at John Gray 2014 Okay. Α. where they performed the meta-analysis on 23 What's your basis for concluding 23 24 that that's the rate for native tissue 24 patients who underwent an anterior or

Page 150 Page 152 1 posterior native tissue repair and sexual 1 and then we can compare it to Lowman to 2 function, which is probably more similar 2 see how many of them are posterior 3 to the Lowman study, they reported an 18 3 repairs, I quess. 4 percent worsening of dyspareunia 4 Q. Do you have any other basis for 5 postoperatively. 5 stating that the de novo dyspareunia rate 6 You want to finish that 6 with Prolift is similar in native tissue repair besides the Weber, which is only 7 7 sentence? 8 8 Α. With a 4 percent de novo rate. posterior, besides John Gray, which only 9 9 So a 4 percent de novo rate in a found a 4 percent de novo rate? Do you have any other studies for your basis? 10 study that you said is most likely similar 10 to the Lowman study, a 4 percent de novo A. The Cochrane review shows that 11 11 rate, that's what your report says, right? 12 12 they're similar with transvaginal mesh. They did show that, but with Q. As we already looked at the 13 13 posterior repair with other studies, there Cochrane review recommends against using 14 14 has been a higher reported rate. the Prolift and Gynemesh PS repair as a 15 15 So, the Lowman study that you 16 16 primary surgical intervention for prolapse cited and that looked at Prolift found a repair, right? 17 17 18 17 de novo dyspareunia and you just read 18 A. And I've agreed to you that about a study that you said is most 19 19 transvaginal mesh is not the procedure for 20 similar to it and found a 4 percent de 20 every single patient, correct. 21 novo rate. 21 For the majority of patients, Q. 22 My question to you is when you 22 riaht? 23 counsel your patients, do you tell them 23 MR. ROSENBLATT: Object to form. 24 that the Prolift de novo dyspareunia rate 24 A. That depends on the patient Page 151 Page 153 is up to 400 percent higher with Prolift 1 population, I guess, that you're seeing. 1 Q. The Cochrane review concludes 2 and Gynemesh PS or --2 3 3 MR. ROSENBLATT: Object to form; that Prolift and Gynemesh PS in 4 lack of foundation; mischaracterization. 4 transvaginal-based mesh repairs shouldn't 5 A. I base that on one study. This 5 be used in most patients, if any; isn't 6 is one study. I base this on the Cochrane 6 that correct? 7 review which says that they're equal. 7 A. In 2016, they conclude that it Q. You cited both of those studies 8 8 should not be a primary repair, and I will 9 9 in your report, right? agree with you it is not the most common 10 10 primary repair that I perform in my A. I did. 11 In your report you state that 11 patient population. there was a 4 percent de novo rate and you And in the Lowman study, I just 12 12 just characterized that study from John 13 13 would like to comment also that although Gray as being most similar -the de novo dyspareunia rate was at 17 14 14 percent, there was still 83 percent of 15 I said more similar. 15 Α. 16 To Lowman, right? Because the 16 respondents with de novo dyspareunia would other study you cited to, Weber, was have the procedure done again. So 17 17 specifically looking at posterior repair although they were having some de novo 18 18 which necessarily has a higher dyspareunia dyspareunia, they would still do the 19 19 20 surgery again. rate, right? 20 21 A. So, I don't remember in John 21 MR. BENTLEY: I'm going to move 22 Gray of how many of these patients had 22 to strike. That was not responsive. posterior repairs, so I would need to look 23 23 I'm sure your counsel will 24 at that number. So we can look at that 24 clarify that.

Page 154 1 1 1 1 1 1 1 1 1	r			1
2 clarifying de novo dyspareunia. 3 MR. BENTLEY: He was not 4 clarifying de novo dyspareunia. 5 BY MR. BENTLEY: 6 Q. Doctor, approximately how many 7 Prolift kits do you think you implanted 8 when it was still available? 9 A. Guesstimate about 50. 10 Q. And how many let's talk about 10 how you would have got to the estimate. 11 how you would have got to the estimate. 12 How many transvaginal let's 13 back up. 14 We did percentages. 15 On average, how many women are 16 you treating per year for prolapse? 17 Let's go back even farther. 18 On average how many women do you 19 see per year that are suffering from 20 prolapse? 21 A. New patients or total? 22 Q. And of the five or six hundred 3 women you see per year that are suffering 4 from prolapse, how many of those women do 5 you undergo a surgical intervention to 6 treat the prolapse? 7 A. So, about 30 percent of the 8 patients, somewhere along the 11 line probably end up choosing surgery 12 these days. Gross numbers. 14 Q. So, is it fair to estimate that 15 Q. So, is it fair to estimate that 16 prolapse? 17 A. Something like that, yeah. 18 Q. And we've already looked at 19 approximately 50 percent of those per year 19 the day and the five or six hundred. 20 you're performany this sue repairs, whether it's obliterative or 10 transvaginal-based implantation, did that 10 transvaginal-based implantation, did that 10 transvaginal-based implantation, did that 11 transvaginal-based implantation, did that 12 group comprise approximately 200 repairs, whether it's obliterative or 14 ansuraginal-based implantation, did that 15 ansuraginal-based implantation, did that 16 proup comprise approximately 200 and proup cream of the transvaginal mesh number would be higher and the transvaginal mesh prolifit are approximately 200 and proup comprise approxim		Page 154		Page 156
MR. BENTLEY: He was not clarifying de novo dyspareunia. MR. BENTLEY: PYMR. BENTLEY: Q. Doctor, approximately how many or Prolift kits do you think you implanted when it was still available? A. Guesstimate about 50. Q. And how many - let's talk about how you would have got to the estimate. How you would have got to the estimate. How many transvaginal let's Me did percentages. We did percentages. On average, how many women are you treating per year for prolapse? Let's go back even farther. On average how many women do you see per year that are suffering from prolapse? A. New patients or total? A. That's a hard number to answer. Page 155 I would say five, six hundred. Q. And of the five or six hundred women you see per year that are suffering from prolapse, how many of those women do you undergo a surgical intervention to treat the prolapse? A. That's a hard number to answer. Page 157 A. So, about 30 percent of the patients, somewhere along the line probably end up choosing surgery these was classed, sirving in propapse? May be provided the five of the patients, somewhere along the line probably end up choosing surgery the source, sirving like that, yeah. Q. So, is it fair to estimate that you're performing approximately 200 that etsial would be provided and you're performing approximately 200 that etsial work in the prolapse? A. Something like that, yeah. Q. And we've already looked at owould be That's our take, per year to treat propapse, low or take, per year to treat papers, make the vissue would be provided that the tissue repairs? A. A carest hard in the tissue repairs, whether it's obliterative or transvaginal-based implantation, did that group comporate with your class approximately 50 percent of precent of you repairs each year compared with your clinical practice today? A. No, I was probably doing more transvaginal mesh procedures and the transvaginal mesh procedure, those were the most likely the patients that we were discussing transvaginal mesh procedure, those were the m	1	MR. ROSENBLATT: He was	1	I'm doing today.
4 clarifying de novo dyspareunia. 5 BY MR. BENTLEY: 6 Q. Doctor, approximately how many 7 Prolift kits do you think you implanted 8 when it was still available? 9 A. Guesstimate about 50. 9 A. Guesstimate about 50. 10 Q. And how many — let's talk about 10 how you would have got to the estimate. 11 Low was un would have got to the estimate. 12 How many transvaginal — let's 13 back up. 14 We did percentages. 15 On average, how many women are 16 you treating per year for prolapse? 16 Let's go back even farther. 17 On average how many women do you 18 see per year that are suffering from 19 prolapse? 10 Q. Total how many women do you 22 g. Total how many women do you 23 see — 24 A. That's a hard number to answer. Page 155 I would say five, six hundred. 2 Q. And of the five or six hundred 3 women you see per year that are suffering from prolapse, how many of those women do you undergo a surgical intervention to teat the prolapse? 7 A. So, about 30 percent of the patients, somewhere along the line — 2 about 30 to 40 — five, six hundred, 30 to 40 percent of your began using the Boston Scientific kit one is that yeah. 4 Q. And over already looked at you're pealirs at that time? 5 A. Yes. Q. And did those native tissue repairs; and that time? 7 A. Something like that, yeah. 9 Q. And did those native tissue road with your repairs each year compared with your repairs each year comparise approximately 50 percent of your repairs each year comparise ach year comparise ach year c	2	clarifying de novo dyspareunia.	2	Q. When you first started using
5 BY MR. BENTLEY: 6 Q. Doctor, approximately how many 7 Prolift kits do you think you implanted 8 when it was still available? 9 A. Guesstimate about 50. 10 Q. And how many — let's talk about 11 how you would have got to the estimate. 12 How many transvaginal — let's 13 back up. 14 We did percentages. 15 On average, how many women are 16 you treating per year for prolapse? 17 Let's go back even farther. 18 On average how many women do you 19 see per year that are suffering from 20 prolapse? 21 A. New patients or total? 22 Q. Total how many women do you 23 see — 24 A. That's a hard number to answer. 25 A. That's a hard number to answer. 26 That's a hard number to answer. 27 A. So, about 30 percent of the 28 patients, somewhere along the line — 29 about 30 to 40 — five, six hundred, 30 to 40 percent of patients somewhere along the line probablye and up choosing surgery 20 these days. Gross numbers. 20 Q. So, is it fair to estimate that 21 you're performing approximately 200 22 you'reperforming approximately 200 23 the surgeries, whether it's obliterative or 24 transvaginal-based implantation, did that 25 transvaginal-based implantation, did that 26 transvaginal-based implantation, did that 27 transvaginal-based implantation, did that 28 transvaginal practice today? 3 (a. Vere 50 percent of your repairs 4 A. Sorry. 4 No, I was probably doing more 4 transvaginal mesh procedures and the — it 4 was lower on a native tissue procedure. 5 So in my patient population, if we were 6 discussing transvaginal mesh procedures and the vere 7 discussing transvaginal mesh and those 8 patients would have chosen a transvaginal 8 mesh. So the native tissue would be lower and the 9 transvaginal mesh number would be higher 9 transvaginal mesh number would be higher 19 about 30 to 40 — five, six hundred, 9 transvaginal mesh procedure. 10 patients would have chosen a transvaginal 11 in the prolapse? 12	3	MR. BENTLEY: He was not	3	Prolift, were you still doing native
5 BY MR. BENTLEY: 6 Q. Doctor, approximately how many 7 Prolift kits do you think you implanted 8 when it was still available? 9 A. Guesstimate about 50. 10 Q. And how many — let's talk about 11 how you would have got to the estimate. 12 How many transvaginal — let's 13 back up. 14 We did percentages. 15 On average, how many women are 16 you treating per year for prolapse? 17 Let's go back even farther. 18 On average how many women do you 19 see per year that are suffering from 20 prolapse? 21 A. New patients or total? 22 Q. Total how many women do you 23 see — 24 A. That's a hard number to answer. 25 A. No, about 30 percent of the 26 you undergo a surgical intervention to 27 A. So, about 30 percent of the 28 patients, somewhere along the line — 29 about 30 to 40 — five, six hundred, 30 to 40 percent of patients somewhere along the line probably end up choosing surgery 20 these days. Gross numbers. 21 A. Something like that, yeah. 22 Q. And of the five or six hundred 33 wou're performing approximately 200 44 you're performing approximately 200 55 surgeries, give or take, per year to treat 66 treat the prolapse? 7 A. Son, about 30 percent of the 8 patients, somewhere along the line probably end up choosing surgery 11 the own many of those women of the you're performing approximately 200 15 surgeries, give or take, per year to treat 16 propapse? 17 A. Something like that, yeah. 18 Q. And we've already looked at 19 approximately 50 percent of those women 19 approximately 50 percent of those per year 19 approximately 50 percent of those per year 19 do And we've already looked at 10 Q. And duffit that gracine about 10 particle today? 11 I would say five, six hundred 12	4	clarifying de novo dyspareunia.	4	tissue repairs at that time?
6 Q. Doctor, approximately how many 7 Prolift kits do you think you implanted 8 when it was still available? 9 A. Guesstimate about 50. Q. And how many let's talk about 11 how you would have got to the estimate. 12 How many transvaginal let's 13 back up. 14 We did percentages. 15 On average, how many women are 16 you treating per year for prolapse? 17 Let's go back even farther. 18 On average how many women do you 19 see per year that are suffering from 20 prolapse? 21 A. New patients or total? 22 Q. Total how many women do you 23 see 24 A. That's a hard number to answer. 25 I I would say five, six hundred. 26 Q. And of the five or six hundred 27 G. And the five or six hundred 28 women you see per year that are suffering 29 from prolapse, how many of those women do 30 you undergo a surgical intervention to 30 to 40 five, six hundred, 30 to 40 percent of patients somewhere along the line 3 about 30 to 40 five, six hundred, 30 to 40 percent of patients somewhere along the line 3 about 30 to 40 five, six hundred, 30 to 40 percent of patients somewhere along the line probably end up choosing surgery 10 these days. Gross numbers. 11 G. And we've already looked at 12 Q. And dwe've already looked at 13 Q. Were 50 percent of your repairs each year compared with your 11 clinical practice today? 2 A. Sorry. 2 A. Sorry. 3 Q. Were 50 percent of your repairs in 2005, 2006 native tissue repairs? 4 A. No, I was probably doing more 1 transvaginal mesh procedures and the it was lower on a native tissue procedure. 2 So in my patient population, if we were 2 doing a vaginal procedure, shose were the most likely the patients that were 2 discussing transvaginal mesh and those 2 patients would have chosen a transvaginal mesh the 2 transvaginal mesh number would be higher 2 back up. 3 do five five patients somewhere along the line 3 about 30 to 40 five, six hundred, 30 to 4 from prolapse, how many of those women do 5 you undergo a surgical intervention to 5 you be percent of patients somewhere alo	5	BY MR. BENTLEY:	5	·
7 Prolifit kits do you think you implanted 8 when it was still available? 9 A. Guesstimate about 50. 10 Q. And how many let's talk about 11 how you would have got to the estimate. 12 How many transvaginal let's 13 back up. 14 We did percentages. 15 On average, how many women are 16 you treating per year for prolapse? 16 The Let's go back even farther. 17 Let's go back even farther. 18 On average how many women do you 19 see per year that are suffering from 19 prolapse? 21 A. New patients or total? 22 Q. Total how many women do you 23 see 24 A. That's a hard number to answer. Page 155 1 I would say five, six hundred. 2 Q. And of the five or six hundred 3 women you see per year that are suffering 4 from prolapse, how many of those women do 5 you undergo a surgical intervention to 6 treat the prolapse? 7 A. So, about 30 percent of the 7 patients, somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 4 of percent of patients some		O. Doctor, approximately how many	6	O. And did those native tissue
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3 women you see per year that are suffering 4 from prolapse, how many of those women do 5 you undergo a surgical intervention to 6 treat the prolapse? 7 A. So, about 30 percent of the 8 patients, somewhere along the line 9 about 30 to 40 five, six hundred, 30 to 10 40 percent of patients somewhere along the 11 line probably end up choosing surgery 12 these days. Gross numbers. 13 Q. So, is it fair to estimate that 14 you're performing approximately 200 15 patients per year, or did you surgically 16 treat approximately 200 women per year 17 that suffered from prolapse throughout 18 your career, do you think? 19 A. Something like that, yeah. 10 Q. And you started using Prolift 11 around 2006 or 2007, correct? 12 A. Something like that, yeah. 13 Q. And you began using the Boston 14 you're performing approximately 200 15 surgeries, give or take, per year to treat 16 prolapse? 17 A. Something like that, yeah. 18 Q. And we've already looked at 19 approximately 50 percent of those per year 20 would be 20 So did you see approximately 200 5 patients per year, or did you surgically 6 treat approximately 200 women per year 7 that suffered from prolapse throughout 9 you started using Prolift 10 Q. And you started using Prolift 11 around 2006 or 2007, correct? 12 A. Something like that, yeah. 13 Q. And you began using the Boston 14 Scientific kit once it was available 15 because it had better apical support, 16 right? 17 A. That's correct. 18 Q. And during that time frame when 19 approximately 50 percent of those per year 20 would be 20 Scientific kit was available, it's your				
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these days. Gross numbers. Q. So, is it fair to estimate that you're performing approximately 200 surgeries, give or take, per year to treat prolapse? A. Something like that, yeah. Scientific kit once it was available because it had better apical support, right? A. Something like that, yeah. A. That's correct. Q. And we've already looked at approximately 50 percent of those per year would be 12 A. Something like that, yeah. 13 Q. And you began using the Boston 14 Scientific kit once it was available 15 because it had better apical support, 16 right? 17 A. That's correct. 18 Q. And during that time frame when 19 you used Prolift before the Boston 20 Scientific kit was available, it's your		•		•
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21 A. So you're asking me what my 21 testimony that you used a larger		•		
22 numbers are today. 22 percentage of transvaginal mesh-based kits 23 during that time period?		•		
23 Back in 2005, '6, '7, '8, I was 23 during that time period? 24 doing more transvaginal procedures than 24 A. Than I do today, yes.		, , , , , , , , , , , , , , , , , , ,		•
ZT A. Illali I do today, yes.	47	domy more dansvaginal procedures than	4 T	A. Hall I do today, yes.

Page 158 Page 160 1 Did you also use a larger 1 occurrence was balanced against a lower 2 percentage of abdominal sacrocolpopexy 2 prolapse occurrence rate in the patients 3 3 undergoing mesh surgery compared with procedures at that time? those undergoing sacrospinous fixation." 4 4 A. I think that has increased over 5 5 Q. And what's your opinion as to the years. 6 6 what the acceptable exposure rate is? (Pause.) 7 (Exhibit Winkler 14, Halaska 7 We discussed before that on 8 8 article, was marked for average if we're going to -- what we're 9 9 identification, as of this date.) going to see, we're going to see about a 10 to 12 percent exposure rate. This was 10 BY MR. BENTLEY: 10 a 20.8 percent exposure rate. 11 Q. Doctor, I'm handing you what's 11 been marked as Exhibit 14, and it's a But let's check if this -- if 12 12 study by Michael Halaska. they were anterior or posterior meshes 13 13 14 Do you see that? 14 placed. 15 A. Yes. 15 Q. So, regardless, this study is evidence of an exposure rate higher than 16 16 Q. I'll represent to you that this what you feel is the true exposure rate? study is cited in your Gynemesh Prolift 17 17 18 report on page 33. 18 You're not letting me look 19 A. Yes, okay. 19 through the study. 20 Q. And on page 33 you cite this 20 Q. My question, Doctor. study for the proposition that: "Prolapse 21 21 No, if there was mesh placed 22 repairs have demonstrated no statistically anterior and posteriorly, I previously 22 23 significant difference in vaginal length 23 testified that we may see up to a 24 24 or contraction, de novo dyspareunia, 24 percent acceptable rate. Page 159 Page 161 sexual function or pelvic pain." 1 So it's your testimony that the 1 acceptable rate for anterior and posterior 2 Do you see that? 2 A. Yes, I do. 3 3 placement of mesh is 24 percent? 4 And we've already looked at some 4 We're going to see it's at 10 to 5 studies that showed increased de novo 5 12 percent in each compartment that we put 6 dyspareunia with mesh which you disagreed 6 mesh in and we, if we're going to put mesh 7 with though, right? 7 in transvaginally in two compartments, Overall I disagree with, yes. 8 then I would expect to see a higher rate. 8 Α. 9 And this study actually is 9 Q. You would expect to see a 24 10 titled "A multicenter randomized 10 percent, is that your opinion? 11 perspective controlled study comparing 11 A. If I add up 12 plus 12, you can sacrospinous fixation and transvaginal 12 12 get up to 24. 13 mesh in the treatment of post-hysterectomy 13 Q. I appreciate that. I'm trying 14 vaginal vault prolapse." to figure out what your opinion is and 14 Do you see that? what you intend to testify to the jury. 15 15 16 The title? 16 Is it your opinion that if Α. there's an anterior and posterior mesh 17 Yes. 17 O. Yeah, I see the title. repair, you intend to testify that the 18 Α. 18 exposure rate is 24 percent? 19 Q. And the conclusion is --19 A. I can say that you can see in up 20 actually, in the results the authors note 20 to a 24 percent exposure rate. 21 that the mesh exposure rate was 20.8 21 22 22 Q. I'm not looking for the highest percent. possible range, Doctor. I'm just trying 23 Yeah, and I like what the 23 24 conclusion says: "Mesh exposure 24 to figure out what your opinion is as to

the true exposure rate of Prolift. It's important for the safety profile, right? MR. ROSENBLATT: Object to the form and the use of the "true rate." Q. What's the actual rate of mesh posterior repair in prolapse, based upon your literature review? A. So this was a study both anterior and posterior dissections of insertions where total mesh were performed. So, you're going to see a higher exposure rate when you have a total mesh placed in anterior and posteriorly than if you're only placing it in one compartment. Q. I appreciate that. Based upon your literature review and your clinical experience, what do you anticipate the exposure rate to be for women that have had an anterior and posterior repair with mesh? A. I think you can see somewhere Page 163 1 A. Yes, I do. Q. And then they note: Of the 20.8 exposures, 63 percent were treated by surjical resection." Do you see that? A. That's 10 of the 28. That's not the entire cohort. Q. 62 percent of the exposures were treated with surgical resection, right? Of these exposures, 10 or 62.5 percent were treated by surgical resection, right? A. Just let's go with the numbers. 20.8 percent as compared with the number of patients is Q. 28? We can see the percentages, Doctor. A. 20 percent of I got to do 20 percent of 79. So it's about 14 patients. So they're going to say 10 of the 14 patients were treated by surgical resection." A. That's 10 of the 28. That's not the entire cohort. Q. 62 percent of the exposures were treated with surgical resection, right? A. Just let's go with the numbers. 20.8 percent as compared with the number of patients is Q. 28? We can see the percentages, Doctor. A. 20 percent of I got to do 20 percent of 79. So it's about 14 patients. So they're going to say 10 of the 14 patients were treated with surgical resection. However, it states that only one quarter were symptomatic. So why were they doing surgery	164
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23 posterior repair with mesh? 24 A. I think you can see somewhere 23 one quarter were symptomatic. 24 So why were they doing surgery Page 163	
24 A. I think you can see somewhere 24 So why were they doing surgery Page 163	
Page 163 Page	
	165
1 around the 24 up to the 24 percent 1 in asymptomatic patients?	103
2 range, 20 to 24. 2 Q. What question are you answering,	
3 Q. Okay. And this study, Halaska 3 Doctor?	
4 found a 20 percent exposure rate, which is 4 A. I'm just commenting on the study	
5 consistent with your testimony as to the 5 that we're talking about.	
6 exposure rate for anterior and posterior 6 Q. I didn't ask for you to comment	
7 repair using mesh, right? 7 on the study. I appreciate that. I'm	
8 A. If you're going to place an 8 sure we'll have plenty of comment coming	
9 anterior and posterior mesh in, yes. 9 up.	
10 Q. And this study there is a 12 10 20.8 percent of the women in the	
11 percent revision? 11 study had exposure, correct?	
12 MR. ROSENBLATT: Object to form. 12 A. Correct.	
13 That misstates what the study finds. 13 Q. And of those 20.8 percent of the	
14 A. Where do you see that? 14 women that had exposure, 62.5 percent of	
15 Q. If you turn to 601.e5 you'll see 15 them underwent surgical resection, right?	
16 at the bottom 16 A. Okay.	
· · · · · · · · · · · · · · · · · · ·	
, , , , , , , , , , , , , , , , , , ,	
19 If you'll turn to 301.e5 on the 19 A. So, 10 of the 80 patients, 10 of	
20 very bottom right they note: "The vaginal 20 the 79 patients, I think that's where	
21 mesh exposure after one year in the mesh 21 you're getting your number from, right?	
22 group was 20.8 percent, one quarter of 22 Q. I'm not counting patients.	
23 which were symptomatic." 23 What's .62 times .2? 24 A. I understand how you're getting	
24 Do you see that? 24 A. I understand how you're getting	

Page 166 Page 168 1 to that number. 1 But I don't know what the 2 2 So 12 percent. counseling was with these patients. 3 3 Q. So just do you agree with me That's what I'm testifying to. 4 that in this study specifically, they 4 MR. ROSENBLATT: Let's slow down 5 found approximately a 12 percent revision 5 for the court reporter. 6 6 rate? BY MR. BENTLEY: 7 7 Q. You know that 20.8 percent of Α. I do and I will comment that it 8 8 seems that they were operating on patients the women had mesh sticking out of the 9 who were asymptomatic with their exposure. 9 body, right? 10 And those patients that chose to 10 A. It was in the vagina. They may undergo a surgical revision procedure not even have known it. 11 11 decided to do that, right? 12 12 O. And 12 percent of the women We don't know if they chose to decided to have the mesh that was sticking 13 13 do that or it was recommended by their 14 14 out surgically removed, right? Twelve physician at the time. percent of all of the women in this study 15 15 Patients have to undergo a 16 chose to have mesh that was sticking out 16 consent process for a surgical revision, surgically removed? 17 17 18 right? 18 Α. Yes. 19 19 Q. So it's a 12 percent surgical Α. Yes. 20 Q. It's their decision whether or 20 revision in this study, which whether or not to undergo a revision surgery, right? 21 21 not it was symptomatic, still 12 percent 22 of the women underwent a revision surgery, Agreed. 22 Α. 23 So these patients, for whatever 23 right? Q. 24 reason, decided to undergo a revision 24 A. And once again, there is no Page 167 Page 169 procedure, right? 1 question and I'm not going to doubt that 1 patients do need to go back to the 2 So, our understanding at this 2 3 3 point in time, and I've stated this operating room for exposures. 4 myself, that we were doing some surgical 4 Q. What's your opinion as to the 5 procedures on asymptomatic patients when 5 rate of surgical revision for women that 6 we thought the mesh exposure needed to be 6 undergo Prolift repair, for anterior and 7 removed, and we subsequently learned that 7 posterior? you don't need to operate on every single 8 8 A. What's the percentage of 9 9 mesh exposure. I can't comment -- all I patients undergoing revisions? 10 can comment here is that one-quarter of 10 Yes. Q. 11 them were symptomatic. So only five Α. I don't have a total number for 11 percent of the patients were symptomatic. 12 12 that. So if 5 percent of 80 is symptomatic, it's 13 13 Do you have an estimate or an a lower number than 10. opinion as to what the revision rate is 14 14 15 You're critical of women for patients that undergo an anterior only 15 16 choosing to undergo a surgical revision 16 Prolift repair? 17 procedure because they have mesh sticking 17 I would think that the revision out of their body? rate is going to be somewhere around --18 18 I'm not critical of that. 19 A. 19 it's a hard question to answer because it depends on if patients were symptomatic 20 They chose to do that, right? 20 Q. and if the patients were sexually active 21 I'm saying it's not absolutely 21 22 medically necessary, but they can 22 and if it was bothersome to them. So I 23 choose --23 can't give an exact number, but I -- or an 24 But they can choose that, right? 24 exact percentage because it depends on the Q.

1	Page 170	1	Page 172
1 2	patient population that you're choosing, but it's going to be lower than the	2	Q. And you're a member of these societies, right?
3	exposure rate.	3	A. Yes.
4	Q. So something lower than 20	4	Q. They're reputable societies,
5	percent?	5	right?
6	A. Well, we discussed already that	6	A. Yes.
7	I think that if it's in one compartment,	7	Q. And this committee opinion is
8	that was your question, that it's about a	8	titled "Vaginal Placement of Pelvic Mesh
9	10 to 12 percent. So I think it's going	9	For Pelvic Organ Prolapse"; is that
10	to be a somewhat lower than a 10 to 12	10	correct?
11	percent number that was quoted in this	11	A. That is correct.
12	study. And once again, they had mesh	12	Q. And on page 4, ACOG and AUGS are
13	placed anterior and posterior.	13	answering the question: "Who are the best
14	Q. Then with respect to the	14	patients for transvaginally placed mesh?"
15	posterior repair, do you have an opinion	15	Do you see that?
16	or estimate as to what percentage of women	16	A. Yes.
17	undergo a revision procedure?	17	Q. And the authors note that: "Few
18	A. For posterior only, I would say	18	data exist as to who are the best patients
19	somewhere around, once again the exposure	19	for transvaginally placed mesh."
20	rate is somewhere in that vicinity and	20	Is that correct?
21	that range that and then it would be	21	A. I agree with that statement.
22	lower as well for posterior than the 10 to	22	Q. And this is in 2011, right?
23	12 percent.	23	A. That is correct.
24	Q. What vicinity or range?	24	Q. Okay. Five years before the
	Page 171		Page 173
1	A. The mesh exposure rate of about	1	Cochrane Maher review that we looked at
2	10 to 12 percent per compartment.	2	today, right?
3	(Exhibit Winkler 15, The	3	A. That's correct.
4	American College of Obstetrics and	4	Q. And the authors continue:
5	Gynecologists Committee Opinion, Dated	5	"Pelvic organ prolapse vaginal mesh
6	December 2011, was marked for	6	
		U	repairs should be reserved for high risk
7	identification, as of this date.)	7	repairs should be reserved for high risk individuals in whom the benefit of mesh
	identification, as of this date.) BY MR. BENTLEY:		•
7		7	individuals in whom the benefit of mesh
7 8	BY MR. BENTLEY:	7 8	individuals in whom the benefit of mesh placement may justify the risk, such as
7 8 9	BY MR. BENTLEY: Q. I'm going to hand you, Doctor,	7 8 9	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse,
7 8 9 10	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15.	7 8 9 10	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or
7 8 9 10 11 12 13	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion	7 8 9 10 11 12 13	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude
7 8 9 10 11 12 13 14	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes.	7 8 9 10 11 12 13 14	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct?
7 8 9 10 11 12 13 14 15	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this	7 8 9 10 11 12 13 14 15	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data
7 8 9 10 11 12 13 14 15 16	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right?	7 8 9 10 11 12 13 14 15 16	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to
7 8 9 10 11 12 13 14 15 16 17	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me	7 8 9 10 11 12 13 14 15 16 17	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve
7 8 9 10 11 12 13 14 15 16 17 18	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me look through it a second.	7 8 9 10 11 12 13 14 15 16 17 18	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs in the
7 8 9 10 11 12 13 14 15 16 17 18 19	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me look through it a second. (Perusing document.)	7 8 9 10 11 12 13 14 15 16 17 18	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs in the anterior compartment, excuse me, and
7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me look through it a second. (Perusing document.) Yes, I'm familiar with this.	7 8 9 10 11 12 13 14 15 16 17 18 19 20	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs in the anterior compartment, excuse me, and they're commenting on that back in 2011
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me look through it a second. (Perusing document.) Yes, I'm familiar with this. Q. And did you review this opinion	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs in the anterior compartment, excuse me, and they're commenting on that back in 2011 too.
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me look through it a second. (Perusing document.) Yes, I'm familiar with this. Q. And did you review this opinion in preparation of your Prolift and	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs in the anterior compartment, excuse me, and they're commenting on that back in 2011 too. Q. What question were you
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. BENTLEY: Q. I'm going to hand you, Doctor, what is being marked as Exhibit 15. This is the committee opinion from AUGS and ACOG dated December 2011; is that correct? A. Yes. Q. You're familiar with this opinion, right? A. I just got to remember let me look through it a second. (Perusing document.) Yes, I'm familiar with this. Q. And did you review this opinion	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse, particularly the anterior compartment, or with medical comorbidities that preclude more invasive and lengthier open and endoscopic procedures." Is that correct? A. So it's consistent with the data that transvaginal mesh has been shown to subjectively and objectively improve outcomes for anterior repairs in the anterior compartment, excuse me, and they're commenting on that back in 2011 too.

Page 174 Page 176 1 Did I read that correctly, 1 high risk, are they? Is that your 2 2 testimony? Doctor? 3 3 A. You read that correctly. A. Every single individual is not 4 And is that conclusion 4 Q. high risk. 5 consistent with what the Cochrane review 5 Q. Right. 6 6 A. I am trying to quantify what five years finds after reviewing 37 RCTs? 7 A. Well, that's why I was 7 high risk is. 8 mentioning what the Cochrane review said, 8 Well, the authors here state 9 that there has been shown to be subjective 9 that the mesh should be reserved for high risk individuals, right? 10 and objective outcomes in the anterior 10 compartment using transvaginal mesh in the 11 11 Yes. 12 Cochrane review. 12 Q. Okay. And they're making a ACOG and AUGS in 2011 concluded delineation that this mesh isn't for 13 13 O. everybody; isn't that fair? 14 that mesh like Prolift and Gynemesh PS 14 15 placed transvaginally should be reserved 15 A. I've never -- I've always said that this mesh is not for everybody. for high risk individuals; is that 16 16 correct? Right. 17 17 Q. 18 A. I don't know if they concluded 18 Not disagreeing with you there. Α. that. It doesn't say. I think that is So you agree with their opinion 19 19 Q. 20 one of their -- it's a --20 that pelvic organ prolapse vaginal mesh 21 Well, let's look at it again. 21 repair should be reserved for high risk 22 They state: "Pelvic organ prolapse 22 individuals? 23 vaginal mesh repair should be reserved for 23 MR. ROSENBLATT: Object to form. 24 high risk individuals." 24 And just the lack of the completeness. Page 175 Page 177 Correct? 1 I agree that the pelvic floor 1 mesh is not for everybody. Their 2 A. So we're going to look under 2 3 3 "Recommendations"? recommendation is to reserve it for high 4 4 risk individuals and who the benefit of What page are you on? 5 We're still on page 4. 5 mesh placement may justify the risks. Q. 6 Yes, so they were saying who are 6 They don't define what a high 7 the best patients for transvaginally 7 risk individuals is, but later on they'll placed mesh and if you look on the 8 give such as individuals with recurrent 8 9 following page that --9 prolapse or with medical comorbidities Hold on. 10 that preclude more invasive and lengthier 10 Q. 11 Okav. 11 open and endoscopic procedures. Α. Just because you have recurrent 12 Stick with the question. 12 They state: "Pelvic organ prolapse doesn't mean you're a high risk 13 13 prolapse vaginal mesh repairs should be patient in a surgical procedure. 14 14 reserved for high risk individuals in whom And I appreciate that. 15 15 16 the benefit of mesh placement may justify 16 And you agree with that the risk." conclusion, is what you're saying? 17 17 A. I agree you need to take that 18 Correct? 18 into consideration when you are discussing 19 A. That's in every single patient. 19 You're going to run a risk-benefit profile your transvaginal mesh procedures with 20 20 with them, and you want to try to do a your patients and I think that is why 21 21 we're doing the 522 studies today. 22 procedure where the benefits outweigh the 22 23 risks, yes. 23 Let me re-ask it. 24 Q. Every single individual is not 24 Doctor, do you agree or disagree

4. I agree, with a modifier. And my modifier is what is considered high my modifier is what is considered high risk? And that is where you need to have that discussion with the patient. are you considering high risk medical comorbidities? Are you considering high risk medical risk? And they gave some guidance, but not absolute guidance. 10. You would think that let's say this. 11. You probably have the same definition of high risk as ACOG and AUGS in this circumstance, don't you, Doctor? 12. A. You're asking me to make an assumption, and I've stated that yes, transvaginal mesh should not be placed in every single patient. 12. Q. It should be reserved for patients who you have a discussion of the risk-benefit profile to see if and they say that too, where the benefit of mesh placement may justify the risk. 12. A. It should be reserved for patients who you have a discussion of the risk say that too, where the benefits of mesh placement may justify the risk. 12. A. It should be reserved for bapatient, the risks should not be outweighed the standard risk-benefit discussion is that the benefits should all always outweigh the risks. 12. That's the standard risk-benefit discussion is that the benefits should all always outweigh the risks. 13. This is intuitively known that you should be discussion is that the benefits of mesh patients. You said it yourself. 14. Q. Why don't you discuss the statement that this mesh should be reserved for high risk individuals, and we can talk about the definition of that, but you agree with the statement or disagree with the should and they gave some guidance, but the should be discussion in the reserved the patient. You should be discussion in your report? 12. A. This is intuitively known that you should be discussing risks and benefits of particular procedures with patients. You said it yourself. 13. Q. Why don't you discuss the statement that this mesh should be reserved for high risk individuals that you've just testified you agree to, why you've just testified			-,	- ,	
A. Lagree, with a modifier. And my modifier is what is considered high risk? And that is where you need to have that discussion with the patient. are you considering high risk medical comorbidities? Are you considering high risk risk age? Are you considering high risk is controlled to got office the medical properties. A controlled risk age aging and the properties of your define wat high risk but you conscient high risk is controlled properties. A controlled risk aging and patient properties aging and risk age. A. Your asking me to make an assumption, and I've stated that yes, transvaginal mesh should not be placed in every single patient. Q. It should be reserved for high risk individuals that you report? A. You're asking me to make an assumption, and I've stated that yes, transvaginal mesh should not be placed in every single patient. Q. It should be reserved for high risk individuals that you report? A. You're asking me to make an assumption, and I've stated that yes, transvaginal mesh should not be placed in every single patient. A. It should be reserved for high risk individuals that you report? A. It should be reserved for high risk in you reserved for high risk in you reserved for high risk age. That the statement or disease and with the statement or					Page 180
3 my modifier is what is considered high 4 risk? And that is where you need to have 5 that discussion with the patient. are you 6 considering high risk medical 7 comorbidities? Are you considering high 8 risk age? Are you considering high risk 9 recurrence? How are you defining the high 10 risk? And they gave some guidance, but 11 not absolute guidance. 12 Q. You would think that let's 13 say this. 14 You probably have the same 15 definition of high risk as ACOG and AUGS 16 in this circumstance, don't you, Doctor? 17 A. You're asking me to make an 18 assumption, and I've stated that yes, 18 transvaginal mesh should not be placed in 19 every single patient. 20 Q. It should be reserved for high 21 risk individuals, and we can talk about 22 that definition of that, but you agree with 23 the definition of that, but you agree with 24 that conclusion? 1 A. It should be reserved for 2 patients who you have a discussion of the 2 risk benefit profile to see if and they 3 ay that too, where the benefit of mesh 9 patient, the risk should not be 9 outweighed the standard risk-benefit 1 discussion is that the benefits should 1 always outweigh the risks. 1 There's nothing controversial 1 about that, right? 1 A. And they further go on to say 1 the repair of POP should take into account 1 the patient's medical and surgical 1 history, severity of prolapse, and patient 1 preference after education regarding the 1 penefits and risks of the surgical and 2 non-surgical alternatives. 2 Which I agree with. 2 Q. And based upon that, it should 2 be reserved for flight risk individuals 2 be reserved for flight risk individuals 2 be reserved for the placed in 2 patients You said it yourself. 2 Q. Why don't you discuss that in this opinion, right? 3 A. This is intuitively known that 4 you so usale particular procedures with patients. You said it yourself. 3 Q. Why don't you discuss that in your served for high risk individuals that 4 you've just testified you agree to, why 4 don't you discuss that in your report? 4 A. I think I					
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Page 182 1 consideration. 2 Q. I appreciate that. 3 There's a lot of footnotes, 4 we've looked at a lot of them in here. 5 There's 106 footnotes, right? Right? 6 A. Yes, there's 106 footnotes. 7 Q. And nowhere in those 106 8 footnotes do you cite to this committee 9 opinion, right? 10 A. Although you can extrapolate 11 that that opinion is consistent, 12 use of the mesh and I'm stating that. 13 Q. And that opinion is consistent, 14 or you've testified that that opinion is 15 consistent with your opinion, right? 16 MR. BENTLEY: Let me rephrase 17 that a logic many large with that opinion, right? 18 Q. You've testified that you agree 19 with that opinion, right? 10 A. I agree that you need to define 21 what a high risk patient is and then you 22 can have that discussion with them. 23 Q. And once you define high risk 24 patients, the mesh should be reserved for 25 them and not the other patients, right? 26 A. So, I can't comment on anybody 27 else who — what they're counseling their patients. 28 patients, the mesh should be reserved for 29 that can't actually sit in the room with 30 q. When you counsel your patients, do you tell them that you think 31 transvaginal mesh with their 4 patient about when they use a transvaginal mesh procedure. I can comment what they should be counseling their patients. 31 do you'll the tother patients about, but I can't actually sit in the room with cover single doctor when they're taiking a patient about when they use a transvaginal mesh should be reserved for 31 them and not the other patients about, but I can't actually sit in the room with cover yingle doctor when they're taiking a patient about when they use a transvaginal mesh should be counseling their patients. 4 Q. When you counsel your patients, cover your patients, of your patients, of your limit the your should be patients about, but I can't actually sit in the room with cover yinglied doctor when they're taiking a patient about when they use a transvaginal mesh should be reserved for only high risk individuals? 4 Q. Whe			1	
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	2.4			

Page 186 Page 188 used compared with native tissue repair." 1 yes. 1 2 2 Do you see that? And these authors conclude, as 3 3 indicated in the right column in the I see that. abstract, that: "Reoperation for apical I think it's your opinion that 4 4 5 prolapse is more common with transvaginal 5 transvaginal mesh has similar efficacy 6 mesh repair than with sacrocolpopexies and 6 rates as compared to native tissue repair; 7 native tissue repair." 7 is that correct? 8 8 Do you see that? So, transvaginal mesh in the 9 9 That's what it states, yes. anterior compartment has been shown to Α. And they continue: "Incontinence 10 10 have greater subjective and objective procedures are more likely to fail when outcomes. It has not been shown, and I'm 11 11 performed along with prolapse repair than going to agree with you and agree with the 12 12 when performed alone." And the next study, that for apical, which is where 13 13 sentence is: "When mesh is used for they're talking about, reoperation apical 14 14 repair, mesh revision is highest with prolapse as per the Cochrane review, has 15 15 not been shown for that. I agree with 16 transvaginal mesh repair and lowest with 16 abdominal sacrocolpopexy." that statement. 17 17 18 Is that correct? 18 So an apical prolapse repair, 19 Α. That's correct. 19 native tissue repair is more efficacious than transvaginal mesh; is that correct? 20 And that's consistent with what 20 21 we've talked about today and with your 21 MR. ROSENBLATT: Object to form. 22 personal experience, correct? 22 Say that again. Α. 23 Yes. 23 In apical repair, native tissue Α. 24 Q. In your report on page 33, you 24 repair has a lower reoperation rate as Page 187 Page 189 discuss the Dandolu study, but you don't 1 compared to transvaginal mesh? 1 discuss their conclusions regarding higher A. I didn't say that. I said that 2 2 they -- that there's no proven benefit. 3 3 reoperation rate. 4 Once again, I was focusing on 4 That doesn't mean that the failure rate is 5 the title of that subsection of 5 worse, right, in the Cochrane review. 6 "Transvaginal Mesh and Pain." 6 So, in the Cochrane review, if 7 Right. And you provided a 7 they say there's no significant benefit finding from the study regarding pain, but 8 of -- of apical prolapse showing that it's 8 9 you didn't address the authors' conclusion 9 better than native tissue repair, it that reoperation was higher with mesh 10 doesn't mean it's worse. 10 placed transvaginally than with the 11 Q. Well, this study we saw they 11 abdominal sacrocolpopexies, right? found higher reoperation rates with 12 12 Once again, because this was not vaginal mesh compared to native tissue 13 13 discussing efficacy. This was discussing repair, right? 14 14 In this one study, yes. 15 complications. 15 Α. 16 Doctor, if you can please turn 16 And this study is looking -to page 219 to the "Discussion" section. it's your testimony this study is looking 17 17 at apical repair? 18 Α. Okay. 18 19 And the authors in Dandolu are 19 That's what they said, reoperation for apical prolapse in the 20 discussing the results, and three 20 sentences in they note that: "Contrary to conclusion is more common with TVMR than 21 21 22 the popular notion that mesh used 22 with sacrocolpopexies. That's their decreases surgical failure, we found 23 23 conclusion. 24 higher reoperation rates with vaginal mesh 24 Right. Q.

Page 190 Page 192 1 And they continue to discuss 1 those findings in your report, correct? 2 that: "Postoperative mesh complications 2 A. I do. In my report I do discuss 3 3 that pelvic pain and dyspareunia rates are were higher than mesh use particularly 4 similar with vaginal mesh procedures. 4 when combined with incontinence sling 5 surgery." 5 That's one of the findings from 6 6 the study, and that's the only finding you Do you see that? 7 They say they found higher 7 discuss in your report, is that correct, 8 reoperations rates with vaginal mesh used 8 from the study on page 33? 9 9 A. Overall in the study, I have compared with native tissue repair. always maintained that transvaginal mesh 10 So do I -- I am going to assume, 10 and we can go look at the numbers, that has been shown to have better subjective 11 11 the reoperation rates were for recurrence and objective outcomes only in the 12 12 13 as well as mesh exposures, but -anterior compartment. We do not have data 13 O. And in addition to reoperation proving that it has better objective or 14 14 rates, I moved down a little bit in that subjective outcomes in the apical 15 15 paragraph, they're also talking about 16 16 compartment or the posterior compartment. complications. O. I'm going to re-ask my guestion. 17 17 18 Do you see where they say: 18 In your report on page 33 where "Postoperative mesh complications were you're discussing the Dandolu 2016 study 19 19 you discuss the pain findings, correct? 20 higher with vaginal mesh use"? 20 I do discuss the pain findings. 21 Yes, I do. 21 22 22 And you don't address the So, in addition to a higher 23 reoperation rate with the mesh, they also 23 finding that mesh was associated with a 24 found a higher complication rate compared 24 high reoperation rate, do you? Page 191 Page 193 to native tissue repair; is that correct? 1 Once again, not in this subtopic 1 of what we were discussing. This was not 2 A. In this study, they did, yes. 2 a report on the -- or a component of the 3 3 However, since we're talking 4 about studies and what's there, it says: 4 report of the efficacy of apical repairs 5 "Postoperative pain and dyspareunia rates 5 here. 6 were high in all types of prolapse 6 Q. Nowhere else in your report do 7 repairs." Further down it goes to say: 7 you discuss that finding, do you? 8 "Pelvic pain and dyspareunia are 8 Which finding? 9 well-known complications of the POP 9 That vaginal mesh is associated procedures." 10 10 with a higher reoperation rate as compared 11 MR. BENTLEY: Again I move to 11 to native tissue repair. strike the answer beyond what was THE WITNESS: Can you do a 12 12 13 responsive to my question. 13 search of my report? MR. ROSENBLATT: He's just O. I did. It's page 33. That's 14 14 15 explaining his answer. 15 it. MR. BENTLEY: He's just reading 16 16 No, I mentioned before that operation rates with exposures, if you 17 the rest of the article which is --17 THE WITNESS: You're picking out take them into consideration, it's higher. 18 18 Q. I'm not talking about other 19 parts that you want to say. 19 20 BY MR. BENTLEY: 20 operation rates. You're asking me for a total 21 Q. So, there's several findings in 21 Α. 22 this study we've discussed. 22 operation. 23 Yes. 23 In this study that you cited in Α. 24 And you don't discuss any of 24 your report, you provide a discussion of Q.

	Page 194		Page 196
1	the pain rate, but you don't discuss the	1	cherry picking a finding from one
2	higher reoperation rate with transvaginal	2	study in 2016.
3	mesh, do you?	3	On page 33, there's only
4	A. Not for this particular study.	4	favorable finding for him and he
5	However, I have quoted that in other	5	ignores all the other ones, which is
6	studies, and the higher reoperation rate	6	called cherry picking. I'm just
7	is including exposure rates.	7	trying to lock that down.
8	Q. Likewise in your report on page	8	MR. ROSENBLATT: All right.
9	33 where you discuss this study, you also	9	Sorry for interrupting. I was trying
10	don't mention that postoperative	10	to help.
11	complications were higher with	11	MR. BENTLEY: I mean, if there's
12	transvaginally-placed mesh, do you?	12	somewhere else in the report, I stand
13	A. I'm not denying that there's	13	corrected.
14	going to be a higher complication rate	14	Is Dandolu cited somewhere else?
15	when you put in a synthetic. We know that	15	Discussed somewhere else?
		16	
16	already. Overall, it's more surgery,		MR. ROSENBLATT: Look, I'm not
17	you're putting in a foreign body. It is	17	going to argue with you. You can keep
18	intuitively and commonly known that your	18	asking your questions.
19	complication rate is going to be slightly	19	I didn't know if you were
20	increased.	20	talking about the study or the
21	However, the dyspareunia and	21	conclusion because he does discuss
22	pain rates do not seem to be increased.	22	that conclusion.
23	Q. Doctor, you don't discuss in	23	MR. BENTLEY: I think the
24	this section in your report on page 33	24	question's clear.
	Page 195	4	Page 19:
1	where you discuss one of the findings from	1	BY MR. BENTLEY:
2	where you discuss one of the findings from Dandolu from 2016, you don't discuss that	2	BY MR. BENTLEY: Q. On page 33
2	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were	2	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33
2 3 4	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes	2 3 4	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu
2 3 4 5	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no?	2 3 4 5	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33.
2 3 4 5 6	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form.	2 3 4 5 6	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you.
2 3 4 5 6 7	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page	2 3 4 5	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work?
2 3 4 5 6 7 8	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or	2 3 4 5 6 7 8	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your
2 3 4 5 6 7 8	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the	2 3 4 5 6 7 8 9	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question.
2 3 4 5 6 7 8 9	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the report. Nowhere else in the report	2 3 4 5 6 7 8 9 10	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question. A. With the caveat that that was
2 3 4 5 6 7 8 9 10 11	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the report. Nowhere else in the report does he discuss it.	2 3 4 5 6 7 8 9 10 11	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question. A. With the caveat that that was not what I was looking for in that
2 3 4 5 6 7 8 9 10 11 12	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the report. Nowhere else in the report does he discuss it. MR. ROSENBLATT: Look on page	2 3 4 5 6 7 8 9 10 11 12	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question. A. With the caveat that that was not what I was looking for in that subtopic.
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2 3 4 5 6 7 8 9 10 11 12 13 14	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the report. Nowhere else in the report does he discuss it. MR. ROSENBLATT: Look on page	2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question. A. With the caveat that that was not what I was looking for in that subtopic. Q. Because you were looking for cherry-picked findings in that subtopic?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the report. Nowhere else in the report does he discuss it. MR. ROSENBLATT: Look on page 21. MR. BENTLEY: That's Dandolu? Counselor, are you testifying	2 3 4 5 6 7 8 9 10 11 12 13	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question. A. With the caveat that that was not what I was looking for in that subtopic. Q. Because you were looking for cherry-picked findings in that subtopic? MR. ROSENBLATT: Object to form.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	where you discuss one of the findings from Dandolu from 2016, you don't discuss that postoperative mesh complications were higher with vaginal mesh use, do you? Yes or no? MR. ROSENBLATT: Object to form. Are you only asking about page 33 or MR. BENTLEY: Anywhere in the report. Nowhere else in the report does he discuss it. MR. ROSENBLATT: Look on page 21. MR. BENTLEY: That's Dandolu? Counselor, are you testifying that on page 21 the doctor discusses Dandolu? MR. ROSENBLATT: No. MR. BENTLEY: Okay. BY MR. BENTLEY: Okay. BY MR. BENTLEY: Q. On page 33 MR. ROSENBLATT: You're talking	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. BENTLEY: Q. On page 33 A. I'm going to say on page 33 there's no other discussion of the Dandolu results on page 33. Q. Thank you. A. How does that work? Q. A lot easier, to answer your question. A. With the caveat that that was not what I was looking for in that subtopic. Q. Because you were looking for cherry-picked findings in that subtopic? MR. ROSENBLATT: Object to form. A. I was not looking for cherry-picked findings. I quote the Cochrane reviews, and I've admitted to you here today that there has been no proven benefit for apical and posterior repairs. And even according to the Cochrane review

Page 198 Page 200 1 MR. BENTLEY: I move to strike. 1 was higher in this study. I agree with 2 2 There's no question pending. that. 3 3 BY MR. BENTLEY: And to wrap up on this study you 4 4 don't discuss any of those conclusions on Q. Let's look at the conclusions on page 221, Doctor. 5 5 page 33 where you discuss one finding from 6 6 this study or anywhere else in your Okav. 7 The authors begin with: "Pelvic 7 report, right? 8 8 pain and dyspareunia are common complaints So, in my practice I wouldn't 9 after prolapse surgery." 9 even compare sacrocolpopexy to transvaginal mesh. My patients who are 10 And that's consistent with your 10 report and your testimony, right? getting the sacrocolpopexy likely would 11 11 not be candidates for transvaginal mesh. 12 Yes. 12 A. They continue: "Mesh revision On page 33 where you discuss one 13 13 Q. is highest with transvaginal mesh repair finding from the study, you don't address 14 14 and least common with abdominal any of these authors' conclusions, do you? 15 15 On page 33 I do not address 16 sacrocolpopexy without concomitant sling." 16 Correct? 17 17 those findings. 18 Okay. 18 Q. And nowhere else in your report A. do you discuss the study one way or 19 Q. And that's the findings we've 19 20 been discussing, right? 20 another, right? 21 That's true. 21 A. Other places of my report I do Α. discuss the -- where the benefits of mesh 22 22 And they continue: "Reoperation Ο. 23 for apical prolapse is more common with 23 are and where there are none. 24 transvaginal mesh repair than with 24 Once again, I would not even Page 199 Page 201 sacrocolpopexies." 1 entertain to compare sacrocolpopexy to 1 2 And that's what you've been 2 total transvaginal mesh. They are 3 3 testifying to also, right? different patient populations that you 4 A. I testified in this study that 4 would do that on. 5 they did have a higher recurrence rate 5 This is a published article. 6 with the transvaginal mesh, yes. 6 Someone thought it was worth doing a study 7 Q. And they continue: "Overall, 7 and they got published on that very issue, failure rate as measured by any type of 8 8 right? 9 subsequent prolapse surgery and/or pessary 9 A. I agree. I agree. use is also higher with transvaginal mesh 10 Q. And there's fairly strict 10 11 repair compared with sacrocolpopexies." 11 criteria to get an article published; is Do you see that? 12 12 that fair? 13 A. I do see that. 13 A. I didn't say it was a bad study. Q. And do you agree or disagree I'm just saying that in my 14 14 patient population, patients who are 15 with that finding? 15 16 A. I agree, but they did not --16 candidates for sacrocolpopexy are usually they did not specify on the anterior not great candidates for transvaginal 17 17 vaginal wall of where I know where mesh, as per the ACOG guidelines which you 18 18 transvaginal mesh has shown subjective and 19 19 showed me. objective. They're doing an overall and Q. I just need to clean up a 20 20 they're including their apical. So I 21 21 little. I think I asked you these 22 haven't really gone through with that. 22 questions in the previous deposition. But, Doctor, in your experience, 23 So you agree --23 Q. 24 That the overall failure rate 24 do you treat women who have suffered Α.

Page 202 Page 204 1 complications after prolapse repair with 1 if you'd like. 2 transvaginal mesh? 2 Q. When a mesh bunches, ropes or 3 3 Α. Yes. curls, does that increase or cause pain 4 4 for the woman? Q. And in your experience treating 5 those women, have you ever seen mesh 5 A. I don't think roping or curling 6 that's bunched? 6 will cause pain in specific, but I do 7 7 think that increased tension on tissues Α. Yes, I have. 8 8 Were you able to visualize or may cause pain. 9 feel the mesh being bunched prior to doing 9 O. If the mesh is bunched, roped, a revision surgery, or how did you observe curled, does that change the pore geometry 10 10 11 that? 11 of the mesh? 12 So, I can't tell just by feel if 12 A. It may. It may not. Don't A. mesh is bunched. When we go back in and 13 13 know. remove some of the mesh, I can see that 14 14 Q. If the pore geometry is changed such that the mesh's pores collapse, does 15 mesh is bunched up. 15 And do you have an estimate of that change the, potentially change the 16 16 how many times you observed that? inflammatory response? 17 17 18 A. I don't have an estimate for 18 So, I have not significantly seen pores collapsing with these 19 that from when I went back in and do these 19 20 procedures. 20 transvaginal meshes. You know, I have a really nice 21 How many women do you think 21 22 vou've treated for complications from 22 picture to show that we submitted of a 23 having Prolift or Gynemesh PS 23 transvaginal mesh that was placed and then 24 transvaginally implanted? 24 that failed. It was an apical failure. Page 203 Page 205 If I had to guess, around 20. 1 THE WITNESS: Do you have the 1 Α. And how many times do you think 2 2 picture? 3 3 you've observed bunched mesh out of 20 A. There are not too many pictures 4 women that you've treated for 4 that we're going to have on meshes that we 5 complications from these devices? 5 don't take out for complications, but 6 A. I can only specifically recall 6 vou --7 of one episode. I don't remember ones 7 Q. So, if a mesh collapses, the 8 pores -- if the pores collapse after 8 from years ago. 9 9 Q. Doctor, have you ever seen, and roping or curling, is it your testimony 10 this may be the same, have you ever seen 10 that that doesn't affect the inflammatory 11 mesh that's roped when you were treating 11 response? women that have complications from these 12 12 Α. No. If the pore size, for some reason, gets smaller, it may affect the 13 devices? 13 inflammatory response. 14 A. I haven't seen the entire mesh 14 ending up rope -- in one roped. 15 And ultimately that could 15 16 Q. Have you seen part of the mesh 16 increase scarring and potentially cause 17 roped? 17 encapsulation? A. I've seen part of the mesh MR. ROSENBLATT: Objection. 18 18 bunched. I don't know if you want to call 19 19 A. I don't know if encapsulation 20 it bunched, roped. occurs, but potentially it can, but 20 usually we don't see encapsulation with 21 Q. Would you also say it's curled, 21 is that another word for the same these types of tissues because that would 22 22 mean there's no tissue incorporated in the 23 condition? 23 24 I think you can use that term, 24 mesh. So quote/unquote encapsulation is a Α.

Page 206 Page 208 1 little different than --1 A. I can't remember where I got 2 2 that screen shot from. I have pictures of Q. You don't want to see 3 3 meshes and whatnot, so I can't remember encapsulation; that's kind of a bad thing, 4 4 where that came from. right? 5 MR. ROSENBLATT: Object to form. 5 What about the mesh Ο. 6 A. Encapsulation means to me that 6 characteristics table above, do vou know 7 the mesh has not integrated into tissues, 7 where that's from? 8 into tissue really. So that's the way I 8 A. I think it's from Ethicon data, 9 9 define encapsulation. but I can't remember where it was from. So I don't -- I can't define 10 10 Do you have any independent basis other than this screen shot to 11 encapsulation if your mesh -- if a mesh 11 bunches up and why not, because there is verify any of those numbers? 12 12 13 still tissue ingrowth into the mesh. A. Well, there's other papers 13 that -- let me see. I think this is based They're not two separate -- there's still 14 14 on Ethicon data, if I remember correctly. 15 tissue in mesh. 15 16 16 O. Could it be from marketing Q. When we were talking about the Gore-Tex meshes, you said encapsulated and 17 advertisement? 17 18 that was a problem, right? 18 A. It could be. I don't remember A. Right, because there can be no 19 19 where it was from. tissue ingrowth with a Gore-Tex mesh. 20 20 Q. But it's not from a study? 21 There's still tissue ingrowth if 21 Not that I recall. 22 I've seen mesh, quote/unquote, bunched. And there's three columns here. 22 23 Q. It may be decreased if it's 23 It's providing mesh characteristics for three different mesh, correct? 24 encapsulated, to some extent? 24 Page 207 Page 209 If it would be encapsulated, it 1 Α. Correct. 1 2 would be an easier removal and dissection. 2 Q. And the first one is Gynemesh PS 3 3 So we don't see encapsulation of or Prolene Soft, right? 4 these polypropylene meshes. I know it's 4 Yes. Α. 5 been used, but by the strict definition, 5 And that's one of the meshes 6 you don't see that kind of encapsulation. 6 that you were using to treat prolapse, 7 Well, me personally, I don't see 7 right? any of it, but you haven't seen it in your 8 8 Α. Correct. 9 clinical practice, you haven't seen any 9 Q. And that's next one's Prolene 10 encapsulation of mesh? 10 mesh; is that correct? 11 If it's encapsulated, I don't 11 Correct. need to do any dissection around the mesh, And is it your understanding 12 12 and that does not happen when these meshes that that's the mesh that's in the TVT 13 13 14 are folded on each other. products for stress urinary incontinence? 14 15 Doctor, let's look at page 14 of 15 You told me before that there O. are a bunch of different types of Prolene 16 your report. 16 meshes, but as a overall, yes, I would say 17 Okay. 17 Α. And this is a screen shot. that it's more consistent with the Prolene 18 18 19 Where is that from? Where did 19 mesh as opposed to the Gynemesh. 20 you get this screen shot from? 20 How's that? 21 A. I can't remember where I got 21 O. And let's look at the second 22 row. It says "Unit Weight." It's that from. 22 23 Did you take this screen shot 23 milligrams per centimeter squared, I Q. 24 24 believe. And it looks like the yourself?

Page 210 Page 212 1 Gynemesh PS is listed as 4.36 and the 1 area, right? 2 Prolene mesh is almost double at 7.6. 2 A. For different indications. 3 3 Is that correct? Q. And then the tensile strength is 4 4 also -- the tensile strength also shows A. Yeah, the fiber size is 5 different in the Gynemesh PS at like 5 that the Prolene Soft or Gynemesh PS is --3-and-a-half mil and in the Prolene mesh 6 6 has half the tensile strength as the 7 7 Prolene which is used in TVT; is that it's 6 mil. 8 8 Q. So that's going to make it correct? 9 9 heavier, or it's going to make the Α. That's correct. Gynemesh PS lighter than the Prolene mesh 10 10 And have you ever seen any Q. that's in the incontinence product, right? documents discussing whether Ethicon's 11 11 meshes are over-engineered or too strong 12 A. Yes. 12 13 One row below, that's the for the -- unnecessarily too strong for Q. 13 porosity. You can see the percent of the area where they're implanted? 14 14 A. I'm familiar with documents that 15 total area, which is, I guess, an estimate 15 16 of the porosity. Ethicon was looking to see, as we 16 But in your report you discuss discussed before with the VICRYL mesh, to 17 17 18 the Amid classification of largest pore 18 see if there were ways to improve their 19 size, right? 19 TVT slina. 20 A. Yes. 20 0. In the ETH.MESH documents that were provided to you, do you see anything 21 But the porosity here based on 21 22 percent total area is 65 percent for where the company was evaluating whether 22 23 Prolene Soft versus 53 percent in Prolene 23 their meshes were over-engineered? 24 for the TVT, right? 24 What do you mean by Page 211 Page 213 Α. Correct. 1 "over-engineered" am I looking for? 1 Q. Well, you know that these meshes 2 So the Gynemesh PS has a higher 2 3 3 porosity than the incontinence products? were developed for hernia repair, right? 4 Correct. 4 A. Correct. 5 5 The burst strength, do you have Q. And you understand that the 6 any understanding what the burst strength 6 abdominal region has different forces than 7 7 the pelvic region, right? is? 8 8 A. Yes, it's the type of pressure Α. Correct. 9 to put on that will burst out the mesh. 9 Q. And if the abdominal -- a repair Q. How is that -- do you know how 10 in the abdominal region may necessitate a 10 11 that's different from the tear strength? 11 stronger mesh as compared to the pelvis, Tear strength is pulling on the right? 12 12 Α. 13 mesh. 13 A. It depends what the indication is for why you're using the mesh, and the 14 And what's the burst strength? 14 Q. TVT data has overwhelmingly shown safety 15 Would sort of be pushing on the 15 Α. and efficacy with this Prolene mesh. 16 mesh. 16 So you haven't been shown any 17 So the Gynemesh PS is half as 17 O. strong as the Prolene mesh as measured by documents discussing whether or not the 18 18 burst strength; is that correct? mesh was over-engineered for use in the 19 19 20 That's correct. 20 pelvis? A. 21 And they're both implanted in 21 A. I don't remember the word Q. the pelvis, right? 22 22 "over-engineered." 23 For different reasons. 23 I do remember documents that Α. 24 They're both in the same pelvic 24 they were looking to see what a Q.

Page 214 Page 216 lighter-weight mesh would, would different 1 1 So, my understanding is that 2 meshes work, you know, what's out there 2 Gynemesh PS was approved to be placed 3 always to improve on your product. 3 transvaginally, and that was what was used 4 4 Q. I'm just jumping around a little in the Prolift and that's why Ethicon went ahead and did -- and did marketing on it. 5 bit to try and finish up. 5 6 6 A. No problem. So you understand that the 7 MR. ROSENBLATT: Can we go off 7 Prolift was marketed and sold before it 8 8 the record for just one second? was cleared, right? 9 9 MR. BENTLEY: Sure. A. Well, I -- I -- what I 10 (Discussion held off the record.) 10 understand is that the FDA requested additional paperwork two years later 11 BY MR. BENTLEY: 11 regarding when the Prolift procedure, when 12 O. Doctor, when you removed Prolift 12 13 mesh or Prolene Soft mesh from women that Ethicon submitted something and they went 13 were suffering complications, did you ever ahead and submitted and they got the 14 14 send any of those --15 15 approval. 16 MR. BENTLEY: Let me rephrase 16 O. And my question is more narrow, 17 17 and I doubt that this gets in. that. 18 When you removed mesh because a 18 But, assuming you are testifying Q. woman was suffering from complications 19 19 to regulatory compliance, do you think 20 after Prolift or Gynemesh PS and you sent 20 it's appropriate for a company to market a 21 that to a pathologist, did you ever 21 device that hasn't been cleared for 22 request any further analysis besides the 22 marketing for permanent implantation? 23 gross examination? 23 So, I think it was cleared that 24 No, I didn't. I sent to what 24 the trocars and the implantation devices Page 215 Page 217 they would do. I didn't request them not 1 were not cleared. So I did not have a 1 2 to do it, but they traditionally do not do 2 problem with the mesh being marketed. 3 3 one. Q. Right. And my question is a 4 4 little different. Do you think it's appropriate to Q. 5 sell a product that hasn't been approved 5 If a device hasn't been cleared 6 to be marketed for a permanent implant in 6 for marketing, with that assumption, do 7 a woman's body? 7 you think it's appropriate for a medical 8 device company to market it for the 8 MR. ROSENBLATT: Object to form. 9 permanent implantation in women's bodies 9 Did you say "approved" or 10 "cleared"? I just didn't hear it 10 if it hasn't been cleared appropriately? 11 correctly. 11 A. Once again, I think that it was MR. BENTLEY: We did approved. cleared appropriately because we used the 12 12 13 We'll do cleared next. 13 Gynemesh PS transvaginally and this is the 14 MR. ROSENBLATT: All right. same mesh that was being used in Prolift. 14 15 MR. BENTLEY: Thank you. 15 MR. ROSENBLATT: Greg, maybe I 16 A. Do I? Excuse me, say that 16 can help you with this. We're not putting him up to 17 17 again. Do you have an opinion as to offer that opinion. 18 18 whether it's appropriate for a company, a 19 19 MR. BENTLEY: And the problem is medical device manufacturer, to market a there's a number of opinions in here 20 20 product for the permanent implantation in 21 21 regarding regulatory compliance and 22 a woman's body that hasn't been cleared 22 warnings and different stuff and if we 23 for marketing? 23 go down that road, then --24 MR. ROSENBLATT: Object to form. 24 MR. ROSENBLATT: Okay. Well,

Page 218 Page 220 1 then I'll let him keep answering. 1 Regarding complications for 2 MR. BENTLEY: Or not answering. 2 prolapse repair, do you have any 3 3 additional basis for opining as to what MR. ROSENBLATT: You can answer 4 physicians know? Is there any study or 4 however you feel appropriate. 5 THE WITNESS: I guess we got 22 5 something that would be different from 6 6 what we talked about earlier? minutes to do this. 7 7 BY MR. BENTLEY: A. I can -- we can discuss what's 8 8 Doctor, you've offered opinions in the AUGS requirement for residents on 9 that you think the speed at which Ethicon 9 grafts and what -rolled out design upgrades or changes to 10 10 O. And that's what they should their products was appropriate, right? 11 11 know, right? Yes, I think it was appropriate. 12 12 A. I'm not aware of any particular 13 You've opined on the study of asking what doctors exactly know 13 Q. appropriateness of Ethicon's decisions to 14 14 or don't know. 15 market products and changes to markets, 15 Q. Doctor, what's your definition 16 16 of "short-term data"? riaht? 17 17 Α. Yes. MR. ROSENBLATT: Object to form. 18 MR. ROSENBLATT: Object to form; 18 A. So, short-term data is anything less than 12 months follow-up as a general 19 outside the scope. 19 rule, but it depends on how long the total 20 BY MR. BENTLEY: 20 follow-up is to figure out what short is. 21 Q. I want you to assume with me 21 22 that the Prolift kit was not cleared for 22 Q. When you state in your various 23 marketing prior to its introduction to the 23 reports that you're looking for long-term 24 market, okay? 24 data, you're generally looking for Page 219 Page 221 The kit was not approved. The 1 something over one year; is that fair? 1 Α. 2 2 mesh was. Yes, that's fair. 3 3 Right. And so, assuming the There's a couple of different 4 kit's not approved, is it appropriate for 4 definitions of failure for prolapse 5 a company to market it for the permanent 5 treatment that's in the literature and 6 implantation in women's bodies? 6 it's discussed in your report. I just 7 MR. ROSENBLATT: Object to form. 7 want to nail down what you intend to use 8 as your definition for failure in the 8 I just want to caution counsel 9 treatment of prolapse. If you want to 9 that he is not offering an opinion, but since he's eliciting one, then 10 10 refer to page 35, go ahead. 11 vou're free to answer. 11 So, all the stuff needs to be I think it's appropriate for taken into context. The definitions that 12 12 Α. whatever the FDA decided to do at that 13 13 we're using today for failure of prolapse point in time, and I would fall back on has changed, as per my report, from 2001. 14 14 So, the way we define failures 15 their recommendations and how they dealt 15 16 with Ethicon. 16 today is more the composite failure that you were mentioning as opposed to the 17 Doctor, earlier today we talked 17 about different physicians may have stricter NIH guidelines that were 18 18 different knowledge, and you had some 19 19 initially. opinions as to what they should know. 20 So the definition you're 20 Q. adopting is the one from today, the 21 Remember that? 21 22 updated definition? A. Yes. 22 When I look at data today, I 23 Just very limited questioning 23 Q. 24 24 will use that updated definition. here.

	Page 222		Page 224
1	MR. BENTLEY: Doctor, thank you.	1	12 percent?
2	That is all the questions that I have	2	A. Yes, it is.
3	for now. I may have some follow-up.	3	Q. And the Abed systematic review
4	MR. ROSENBLATT: Let's take a	4	also noted that dyspareunia was described
5	quick break.	5	in 70 studies for a rate of 9.1 percent,
6	(Recess taken from 8:12 p.m. to	6	and my question to you is is that figure
7	8:22 p.m.)	7	generally consistent with the 10 to 15
8	EXAMINATION BY	8	percent that you offered or that you
9	MR. ROSENBLATT:	9	testified to in your deposition?
10	Q. Doctor, my name is Paul	10	A. Yes.
11	Rosenblatt. I represent Ethicon Inc. and	11	MR. BENTLEY: Objection;
12	Johnson & Johnson.	12	misstates.
13	We're coming up on our ninth	13	BY MR. ROSENBLATT:
14	hour of deposition testimony.	14	Q. Doctor, you were also asked
15	But, you were asked some	15	about why the ACOG opinion number 513
16	questions about various studies in your	16	wasn't specifically called out in your
17	report.	17	report.
18	Do you recall those?	18	Do you recall that?
19	A. Yes, I do.	19	A. I do recall that.
20	Q. And some systematic reviews were	20	Q. I'm showing you your reliance
21	listed in your report, and others were	21	list.
22	just on your reliance list, correct?	22	Do you see that ACOG committee
23	A. Correct.	23	opinion on your reliance list?
24	Q. For example, a systematic review	24	A. Yes, I do.
	Page 223		Page 225
1	Page 223 that's on your reliance list by Abed:	1	Page 225 Q. And you have hundreds of
1 2		1 2	
	that's on your reliance list by Abed:		Q. And you have hundreds of
2	that's on your reliance list by Abed: "Incidence and management of graft	2	Q. And you have hundreds of citations in your actual report, do you
2	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and	2	Q. And you have hundreds of citations in your actual report, do you not?
2 3 4	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse	2 3 4	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact
2 3 4 5	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic	2 3 4 5	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but
2 3 4 5 6 7	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that	2 3 4 5 6	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your
2 3 4 5 6	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011."	2 3 4 5 6 7	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant
2 3 4 5 6 7 8	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the	2 3 4 5 6 7 8	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance
2 3 4 5 6 7 8	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study.	2 3 4 5 6 7 8 9	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily
2 3 4 5 6 7 8 9 10 11	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of	2 3 4 5 6 7 8 9 10	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not.
2 3 4 5 6 7 8 9 10 11 12	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of the reviews by the Society of Gynecologic	2 3 4 5 6 7 8 9 10 11 12	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not. Q. And so for example, another
2 3 4 5 6 7 8 9 10 11	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of the reviews by the Society of Gynecologic Surgeons.	2 3 4 5 6 7 8 9 10 11 12 13	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not. Q. And so for example, another systematic review by Schimpf titled "Graft"
2 3 4 5 6 7 8 9 10 11 12 13 14	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of the reviews by the Society of Gynecologic	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not. Q. And so for example, another systematic review by Schimpf titled "Graft in mesh use in transvaginal mesh prolapse
2 3 4 5 6 7 8 9 10 11 12 13 14 15	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of the reviews by the Society of Gynecologic Surgeons. Do you recall that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not. Q. And so for example, another systematic review by Schimpf titled "Graft in mesh use in transvaginal mesh prolapse repair. A systematic review from 2016,"
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of the reviews by the Society of Gynecologic Surgeons. Do you recall that? A. Yes. Q. And I'll represent to you that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not. Q. And so for example, another systematic review by Schimpf titled "Graft in mesh use in transvaginal mesh prolapse repair. A systematic review from 2016," was that also a systematic review that you
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	that's on your reliance list by Abed: "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review from 2011." Do you recall reviewing that study? A. I recall. I don't recall the specifics of the study. Q. I'll represent that was one of the reviews by the Society of Gynecologic Surgeons. Do you recall that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And you have hundreds of citations in your actual report, do you not? A. Yeah, I don't remember the exact number, but Q. And there are a significant amount of studies that are on your reliance list, but you didn't necessarily list every single study on your reliance list in the body of your report, fair? A. No, I did not. Q. And so for example, another systematic review by Schimpf titled "Graft in mesh use in transvaginal mesh prolapse repair. A systematic review from 2016,"
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	Page 226		Page 228
1	on.	1	study because you were not, in fact, the
2	I want to come back to this, but	2	primary investigator?
3	I just want to read something in the	3	A. I was not the primary
4	"Discussion" section that states: "Pelvic	4	investigator, and I did not recall this
			- :
5	pain and dyspareunia are well-known	5	particular study.
6	complications of the pelvic organ prolapse	6	Q. And Exhibit 8 under the
7	procedures."	7	"Conclusion," could you read what it
8	Do you see that?	8	states there?
9	A. Yes, I do. That's correct.	9	A. "Pelvic organ prolapse repair
10	Q. Is that statement generally	10	using vaginally-placed Gynemesh PS is safe
11	consistent with your opinion about which	11	with few mesh-related complications. Most
12	complications are well-known or commonly	12	that did occur were successfully treated
13	known to pelvic floor surgeons?	13	in the office. Overall at one year
14	A. Yes, it is.	14	success rate was 84 percent."
15	·	15	·
	Q. I'm going to come back to that,		Q. Is that conclusion based on the
16	Doctor.	16	Gynemesh PS study that involved Dr. Lind
17	I want to show you Exhibit 6.	17	and yourself as a subinvestigator
18	This was the proposal, and you see your	18	generally consistent with your opinions
19	name listed number 3 there?	19	about Gynemesh PS?
20	A. Yes, I do.	20	A. Yes.
21	Q. Did you sign anything on this	21	Q. I want to hand you, hopefully
22	document?	22	counsel has the marked version since I'm
23	A. No, I did not.	23	out of copies here, but Exhibit 21.
24	Q. I want to show you Exhibit 7	24	(Exhibit Winkler 21, Gynemesh PS
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	Page 227		Daga 220
4	Page 227	1	Page 229
1	where you're listed as a subinvestigator.	1	Early Clinical Experience, was marked
2	where you're listed as a subinvestigator. A. Correct.	2	Early Clinical Experience, was marked for identification, as of this date.)
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Page 230 Page 232 changes to the pore geometry depicted in 1 BY MR. ROSENBLATT: 1 2 2 this photograph? Q. Then on page 14 of your report, 3 3 there are some mesh characteristics and a Α. No, I do not. 4 photograph of Gynemesh PS. 4 Doctor, looking at Exhibit 15, 5 Do you see that? 5 the ACOG committee opinion number 513. 6 6 Yes, I do. 7 7 Q. I want you to pull out Exhibit Do you recognize whether or not 8 8 those photographs are consistent with the 15 as well. 9 photographs depicted in this study? 9 Α. Got it. 10 A. Yeah, they're identical in the 10 And also if you could refer to study as in my report. page 16 of your report. 11 11 O. Doctor, I want to hand you 12 12 A. Okay. 13 what's been marked as Exhibit 22. And on page 16, you write: "The 13 rationale for me was to use permanent mesh 14 (Exhibit Winkler 22, color copy 14 for patients who had failed a prior 15 photograph, was marked for 15 identification, as of this date.) 16 prolapse procedure or for post-hysterectomy 16 BY MR. ROSENBLATT: patients with prolapse who were poor 17 17 18 Q. Is this a photograph that you 18 candidates for or did not desire an 19 brought with you to this deposition? 19 abdominal procedure." 20 A. Yes, it is. 20 Do you see that? 21 Q. Could you just describe for the 21 A. Yes, I do. 22 jury what's depicted in this photograph? Is that generally consistent 22 23 So, we can see that there's a 23 with the description, as you understand 24 mesh on the top of the vagina. So we're 24 it, in the ACOG practice bulletin about Page 231 Page 233 looking on an abdominal incision down. 1 patient selection? 1 2 There is a probe in the vagina pushing 2 Yes, it is. 3 3 that -- the vagina up, and we can see that Specifically in the ACOG 4 there's a mesh placed there on top of the 4 practice bulletin, the second bullet point on the last page states: "Pelvic organ 5 5 vagina. 6 6 prolapse vaginal mesh repair should be This was a transvaginally-placed 7 mesh, a Perigee mesh that I recall, where 7 reserved for high risk individuals in whom the patient had a subsequent apical 8 benefit of mesh placement may justify the 8 9 9 failure and then I went back - not by me, risk, such as individuals with recurrent if I remember correctly - and then I went 10 10 prolapse, particularly of the anterior 11 back in to do the recurrent prolapse 11 compartment, or with medical comorbidities that preclude more invasive and lengthier 12 procedure on her. 12 open and endoscopic procedures." 13 And as you can see here, we 13 don't get to see this very often of how Do you see that? 14 14 15 transvaginally mesh is placed in patients 15 Yes, I do. Α. 16 who are not having complaints. There does 16 Q. And is that generally consistent not seem to be any contraction, roping, with what you were telling counsel about 17 17 pulling, banding of the discussing the risks and benefits for each 18 18 19 transvaginally-placed mesh. 19 patient? And do you recall being asked 20 Yes, it is. 20 A. questions about changes to the pore 21 21 And you're certainly not here to geometry? 22 22 tell the jury that pelvic mesh should be used as the primary procedure for every 23 23 A. Yes, I do. 24 And do you see any significant 24 single patient who has pelvic organ

	Page 234	4	Page 236
1	prolapse, are you?	1	removal/revision rate?
2	A. No.	2	A. Yes, it is.
3	Q. And do you rely on a company to	3	Q. If you turn to table 3.
4	provide specifics on patient selection, or	4	Well, Doctor, before we go to
5	do you rely primarily on your surgical	5	table 3, you're not suggesting to the jury
6	experience, practice bulletins, and other medical literature?	6	that when you account for revisions
7		7	associated with mesh erosion or exposure
8	A. I rely on my experience and the	8 9	that a vaginal mesh repair has a lower
9	medical literature predominantly.		rate of reoperations overall compared to
10	Q. And why do you not rely on a	10	native tissue repairs, are you?
11	company to tell you how to practice	11	A. I'm not saying overall that
12	medicine?	12	transvaginal mesh has a lower reoperation
13	A. A company hasn't gone to medical	13	rate, correct.
14	school, hasn't seen patients, hasn't done	14	Q. In fact, you offered that
15	a residency and a fellowship, and operate.	15	opinion in your report when you cited to
16	Q. On page 3 of the ACOG practice	16	the 2006 Maher Cochrane review where you
17	bulletin, it states: "Pelvic pain, groin	17	describe their findings about increased
18	pain and dyspareunia can occur with pelvic	18	total reoperation rates?
19	reconstructive surgery regardless of the	19	A. Correct.
20	use or non-use of mesh."	20	Q. And we'll jump around a little
21	Do you see that?	21	bit, but on page 21 of your report.
22	A. That is correct.	22	A. Yes.
23	Q. And is that generally consistent	23	Q. It states: "The 2016 Cochrane
24	with your opinions about the commonly	24	review found that, quote, there was no
	Page 235		Page 237
1	known risks of all prolapse procedures?	1	evidence of a difference between the
2	A. Yes, it is.	2	groups in rates of de novo dyspareunia,
3	Q. Doctor, if you could pull out	3	end quote. Additionally, the review noted
4	Exhibit 16, that is the Dandolu study	4	that recurrence and rates of repeat
5	again.	5	surgery for prolapse were both lower in
6	A. Yes.	6	the mesh group, although more women in the
7	Q. Now, in your report you cite the	7	mesh group required repeat surgery for the
8	study on page 33?	8	combined outcome of prolapse, stress
9	A. Yes, I do.	9	incontinence, or mesh exposure. It is of
10	Q. And if you look on page 32, what	10	no surprise that using a composite group
11	is the specific heading of that section?	11	for repeat surgery that includes mesh
12	A. "Transvaginal mesh and pain."	12	exposure will be higher in the mesh group."
13	Q. So, is that what you meant when	13	Do you see that?
14	you said you were citing the data specific	14	A. Yes, I do.
15	to transvaginal mesh and pain as it	15	Q. And is that generally consistent
16	applied to this section of your report?	16	with the findings that are described in
17	A. Yes, I do.	17	Dandolu about an increased total
18	Q. And the results state: "Mesh	18	reoperation rate?
19	removal/revision was reported highest in	19	A. That's consistent, yes.
20	transvaginal mesh repair at 5.1 percent."	20	Q. And jumping back to Dandolu
21	Do you see that?	21	table 3, it shows common associated
22	A. Yes, I do.	22	diagnoses during follow-up, and then it
23	Q. And is that percentage generally	23	has dyspareunia and pelvic pain on that
24	consistent with your understanding of the	24	chart.
	consistent four understanding of the		J. 13. 3.

		Page 238	_	Page 240
1	Do you see that?		1	Q. And it's titled "Complication
2	A. I do see that.		2	and Reoperation Rates After Apical Vaginal
3	Q. Which was higher for		3	Prolapse Surgical Repair"?
4	dyspareunia, the native tissue repair or		4	A. Correct.
5	the transvaginal mesh repair?		5	Q. And if you look at table 2, and
6	 The native tissue repair. 		6	you look at the dyspareunia rates for
7	Q. And does the native tissue		7	traditional vaginal repair, sacrocolpopexy
8	repair show 7.5 percent compared to 6.1		8	and mesh kits, do you see any significant
9	percent?		9	differences?
10	A. Yes, it does.		10	A. There are no significant
11	Q. And which was higher, the native		11	differences between the three.
12	tissue repair or the transvaginal mesh		12	Q. And if you look at the total
13	repair, for pelvic pain?		13	complication rates as reported on this
14	A. The native tissue repair was		14	chart in the systematic review, do you see
15	higher at 22 percent versus 16.4 percent.		15	any significant differences?
16	Q. And counsel suggested that there		16	A. No, I do not.
17	might be some cherry picking.		17	Q. Is that chart describing the
18	You're certainly not offering		18	complications generally consistent with
19	these numbers to say that pain and		19	your opinions as it relates to dyspareunia
20	dyspareunia are higher with native tissue		20	and total complications?
21	repairs as they appear in this report, but		21	A. Yes, it does.
22			22	•
	just that overall the studies show that			Q. I'm handing you now what's been
23	there's no significant difference; is		23	marked as Exhibit 18, which is a
24	that fair?		24	systematic review by Maher titled
		Page 239		Page 241
1	MR BENTLEY: Object to	Page 239	1	Page 241 "Anterior Vaginal Compartment Surgery."
1 2	MR. BENTLEY: Object to	Page 239	1	"Anterior Vaginal Compartment Surgery."
2	colloquy. Object to form; leading;	Page 239	2	"Anterior Vaginal Compartment Surgery." (Exhibit Winkler 18, Maher
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2 3 4 5 6	colloquy. Object to form; leading; compound; vague. A. Yes. MR. ROSENBLATT: That's a record.	Page 239	2 3 4 5 6	"Anterior Vaginal Compartment Surgery." (Exhibit Winkler 18, Maher article, was marked for identification, as of this date.) BY MR. ROSENBLATT: Q. Do you see that?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	colloquy. Object to form; leading; compound; vague. A. Yes. MR. ROSENBLATT: That's a record. MR. BENTLEY: Speculation; misstates. BY MR. ROSENBLATT: Q. Doctor, you also cited some other reviews in your expert report. I'd like to hand you now what I've marked as Exhibit 17, which is the Diwadkar systematic review. (Exhibit Winkler 17, Diwadkar article, was marked for identification, as of this date.) BY MR. ROSENBLATT: Q. Are you familiar with this study? A. Yes, I am. Q. And again this is a systematic		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	"Anterior Vaginal Compartment Surgery." (Exhibit Winkler 18, Maher article, was marked for identification, as of this date.) BY MR. ROSENBLATT: Q. Do you see that? A. Yes, I do. Q. And the aim of this study was to review the safety and efficacy of anterior vaginal compartment pelvic organ prolapse surgery, and they described their methodology as reviewing English language scientific literature after searching Pub Med, Medline, Cochrane library and the Cochrane database of systematic review published up to January of 2012. Do you see that? A. Yes, that's correct. Q. It states: "Consistent Level I data support a superior anatomical outcome for polypropylene mesh compared with a

	Page 242		Page 244
1	A. Yes, I do.	1	article, was marked for
2	Q. Is that generally consistent	2	identification, as of this date.)
3	with your opinions?	3	BY MR. ROSENBLATT:
4	A. Yes, it is.	4	Q. Doctor, I'm going to hand you
5	Q. And in all fairness, it says:	5	what's been marked as Exhibit 19, which is
6	"Mesh exposure rate was significantly	6	the "One-Year Objective and Functional
7	higher in the polypropylene mesh group"?	7	Outcomes of a Randomized Clinical Trial of
8	A. Not surprising. Agreed.	8	Vaginal Mesh For Prolapse," by lead author
9	Q. It goes on to state:	9	Andrew Sokol.
10	"Consistent Level I evidence demonstrates	10	A. Yes, I see it.
11	superior subjective and objective outcomes	11	Q. Are you familiar with this
12	following anterior transvaginal	12	study?
13	polypropylene mesh as compared to anterior	13	A. Yes.
14	colporrhaphy."	14	Q. And this is a follow-up to the
15	Do you see that?	15	Iglesia study; is that correct?
16	A. Yes, I do.	16	A. That's correct.
17	Q. And what grade did they give	17	Q. And this study compares Prolift
18	that conclusion?	18	to anterior colporrhaphy?
19	A. Grade A.	19	A. Correct.
20	Q. Is that generally consistent	20	Q. Now, on page 86.e6 they state:
21	with the literature, at least as reported	21	"Of the 32 mesh subjects being Prolift,
22	in 2013?	22	five women or 15.6 percent had mesh
23	A. Yes, that I'm aware of.	23	exposures."
24	Q. And a little further down it	24	Do you see that?
_ '	Q. This a field farther down is		Do you see that.
	Page 243		Page 245
1	states: "Anterior polypropylene mesh had	1	A. Yes, I do.
2	a mesh extrusion rate of 10.4 percent with	2	Q. And it describes the exposures
3	6.3 percent requiring a surgical	3	occurred at two weeks, six weeks, and
4	correction."		
		l 4	subpoint 5 weeks and 2.1 months and were
		4 5	subpoint 5 weeks and 2.1 months and were located along incision lines in the
5	Do you see that?	5	located along incision lines in the
5 6	Do you see that? A. Yes, I do.	5 6	located along incision lines in the anterior compartment and posterior
5 6 7	Do you see that? A. Yes, I do. Q. And is that generally consistent	5 6 7	located along incision lines in the anterior compartment and posterior compartment in two cases?
5 6 7 8	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here	5 6 7 8	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that.
5 6 7 8 9	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today?	5 6 7 8 9	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent
5 6 7 8 9 10	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is.	5 6 7 8 9 10	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures
5 6 7 8 9 10 11	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is:	5 6 7 8 9 10 11	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line?
5 6 7 8 9 10 11 12	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh	5 6 7 8 9 10 11 12	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct.
5 6 7 8 9 10 11 12 13	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective	5 6 7 8 9 10 11 12 13	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the
5 6 7 8 9 10 11 12 13 14	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue	5 6 7 8 9 10 11 12 13 14	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the
5 6 7 8 9 10 11 12 13 14 15	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be	5 6 7 8 9 10 11 12 13 14 15	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of
5 6 7 8 9 10 11 12 13 14 15 16	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased	5 6 7 8 9 10 11 12 13 14 15 16	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct?
5 6 7 8 9 10 11 12 13 14 15 16 17	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior	5 6 7 8 9 10 11 12 13 14 15 16 17	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct.
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh." Do you see that?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct. Q. They continued following the patients. They just stopped
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh." Do you see that? A. Yes, I do.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct. Q. They continued following the patients. They just stopped A. They just stopped enrolling.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh." Do you see that? A. Yes, I do. Q. And is that generally consistent	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct. Q. They continued following the patients. They just stopped A. They just stopped enrolling. Q. And a little further in the
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh." Do you see that? A. Yes, I do. Q. And is that generally consistent with your opinions?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct. Q. They continued following the patients. They just stopped A. They just stopped enrolling. Q. And a little further in the paper it states: "Of the 33 no mesh
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh." Do you see that? A. Yes, I do. Q. And is that generally consistent with your opinions? A. Yes, it is.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct. Q. They continued following the patients. They just stopped A. They just stopped enrolling. Q. And a little further in the paper it states: "Of the 33 no mesh participants, five women, or 15 percent,
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Do you see that? A. Yes, I do. Q. And is that generally consistent with the opinions you've offered here today? A. Yes, it is. Q. And the conclusion is: "Polypropylene anterior compartment mesh offers improved objective and subjective outcomes compared with native tissue repair. However, these benefits must be considered in the context of increased morbidity associated with the anterior polypropylene transvaginal mesh." Do you see that? A. Yes, I do. Q. And is that generally consistent with your opinions?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	located along incision lines in the anterior compartment and posterior compartment in two cases? A. Yes, I see that. Q. Is that generally consistent with your opinions that most exposures will occur at the incision line? A. That's correct. Q. And in all fairness, the investigators of this study stopped the study short due to the predefined rate of mesh exposures, correct? A. That's correct. Q. They continued following the patients. They just stopped A. They just stopped enrolling. Q. And a little further in the paper it states: "Of the 33 no mesh

Page 246 Page 248 1 Do you see that? 1 prolapse and sexual function. 2 Yes, I do. 2 Do you see that? A. 3 So, although the investigators 3 Yes, I do. 4 stopped the study because the exposure 4 What were their results? Q. 5 rate with the Prolift surpassed the 5 With regard to the anterior 6 predefined 15 percent, it would be correct 6 compartment, the use of mesh is associated 7 to say that so did the suture exposures 7 with neither a worsening in sexual 8 8 with the native tissue repairs, correct? function, nor an increase in de novo 9 9 It would be correct to say that, dyspareunia compared with traditional 10 10 anterior colporrhaphy. yes. Q. Is that generally consistent or 11 And a little further down some 11 inconsistent with your opinions? 12 of the findings were that: "There were no 12 statistically significant differences were That's consistent with my 13 13 Α. found between the mesh and no mesh groups 14 14 opinions. 15 with respect to long-term complications." 15 Q. Doctor, you testified earlier that it's somewhat difficult to study or 16 Do you see that? 16 17 Yes, I do. capture true de novo dyspareunia rates in Α. 17 18 And a little further down it 18 studies. Q. 19 states: "No statistically significant 19 Can you just explain why that is 20 differences were found between the mesh 20 for the jury? 21 and no mesh groups with respect to new 21 A. So, dyspareunia rates are 22 onset dyspareunia. The mesh group 1 in 11 22 dependent on several variables. Age has 23 women, or 9.1 percent, versus no mesh 23 something to do with it. Menopause has 24 group 3 out of 14 women, 21.4 percent." 24 something to do with it. Your overall Page 247 Page 249 Do you see that? 1 well-being has something to do with it, as 1 well as the psychosocial situation with 2 Yes, I do. 2 Α. 3 3 Q. Is that generally consistent your partner. We know that as women age, 4 with the opinions you've offered in your 4 the dyspareunia de novo rates increase, 5 report and here today? 5 and overall, however, as women are getting 6 A. Yes, it is. 6 older, they're having decreased sexual 7 And in fact, this study actually 7 Q. activity. shows a higher de novo dyspareunia rate 8 8 Ο. Thank you, Doctor. 9 9 with the anterior colporrhaphy compared to Now I want to look at Prolift in absolute numbers, correct? 10 Exhibit 12, which is the study by 10 11 A. Yes, that's accurate. 11 Damoiseaux, D-A-M-O-I-S-E-A-U-X. But you're not here offering the 12 Q. 12 This is a seven-year Prolift 13 opinion that the dyspareunia rate is 13 study that you were asked about. higher with native tissue repairs, are A. Correct. 14 14 15 15 I want to show you in the you? 16 No, I am not. They're 16 conclusions they state: "Although the equivalent, is my opinion. mesh exposure rate was extremely high, we 17 17 And so, if counsel wanted to found no difference in pain rate or 18 18 accuse you of cherry picking, you could 19 19 dyspareunia between the two groups." have very easily pulled those numbers out 20 Do you see that? 20 to say that the mesh exposure --21 21 Yes, I do. 22 MR. ROSENBLATT: Strike that. 22 And then a little above that in 23 Q. Look at Exhibit 10, which is the 23 table 3 they report complications 24 Dietz and Maher review on pelvic organ 24 comparing mesh versus conventional

Page 250 Page 252 1 procedures. 1 Q. Doctor, in the Altman study that 2 2 was marked as Exhibit 11, counsel went A. That is correct. 3 3 over with you on page 1832 that pain And when looking at mesh versus during sexual intercourse was reported to 4 the conventional procedures, which was 4 5 higher with respect to percentage of pain? 5 occur usually or always by 2 percent of 6 6 It was higher in the the women after colporrhaphy and by 7.3 7 conventional procedure 45 percent as 7 percent after transvaginal mesh surgery 8 opposed to 34 percent in the mesh group. 8 with Prolift and the p-value is 0.07. 9 And what about chronic pelvic 9 Do you see that? 10 pain? 10 A. Yes, I do and that's nonsignificant. 11 Α. Also higher in the conventional 11 12 group, 29 percent as opposed to 15 12 O. Explain what it means when something is not statistically 13 percent. 13 14 Q. And what about de novo pelvic 14 significant. 15 pain? 15 Α. So, it has to -- that number has 16 to happen more by chance, and if we don't 16 Higher in the conventional group than the mesh group. see a number of less than 0.05, we cannot 17 17 18 And in all fairness, 18 say that that result happened just by Q. 19 dyspareunia? 19 chance. 20 Dyspareunia was slightly higher 20 Q. And based on your review of 21 in the mesh group, but at 27 to 25 21 systematic reviews and the Level I 22 literature and randomized controlled percent. 22 23 And de novo dyspareunia? 23 trials, what is your understanding as to Q. 24 Α. Was also fairly equivalent at 10 24 whether or not there's any statistically Page 251 Page 253 percent in the mesh group and 12 percent 1 significant difference in postoperative 1 complications, such as de novo dyspareunia 2 in the conventional group. 2 O. And although this study shows 3 3 or de novo pain, comparing transvaginal 4 that the conventional group had higher 4 mesh to native tissue repairs? 5 rates of, for example, chronic pelvic pain 5 A. I'm not aware of studies that 6 and de novo dyspareunia, you're not using 6 show that there is a statistically 7 this study to say that native tissue or 7 significant difference between the two. conventional prolapse repairs have higher 8 8 Q. But would it be fair to say that 9 rates of pain and dyspareunia, are you? 9 the Level I literature demonstrates that 10 Absolutely not. 10 there are no statistically significant A. 11 And so if you wanted to cherry 11 differences? pick studies, this could be an example of 12 12 MR. BENTLEY: Objection. where you could use percentages to your A. Most importantly it's the Level 13 13 advantage, right? I data that I rely on that shows that 14 14 there is no statistically significant 15 That is correct. 15 Α. 16 But rather than doing that, 16 difference between the two. 17 could you explain why, in fact, you rely 17 And is that consistent with your on Level I literature as opposed to just opinion based on Exhibit 9, which is the 18 18 pulling rates from one study? 2016 Maher Cochrane review where on page 19 19 Right. So, from one study is 18 it states: "There was no evidence of a 20 20 not as good of a study and as high a level 21 21 difference between the groups in rate of 22 as a composite from multiple studies in 22 de novo dyspareunia"? using that data to try to get higher level 23 23 That is correct. And that's 24 results. 24 what I based my previous answer on no

Page 254 Page 256 what's been marked as Exhibit 14. This is 1 difference on the Level I studies. 1 2 2 And was it also true for their the Halaska randomized control trial 3 3 findings about sexual function and quality evaluating Prolift compared to 4 4 of life? sacrospinous ligament fixation. 5 That is true. 5 Do you see that? Α. 6 6 A. Yes, I do. Doctor, you were asked about 7 Exhibit 13, which is the Lowman study 7 And do you see where they state in the results: "No difference in quality titled does the Prolift system cause 8 8 9 9 of life improvement as well as de novo dyspareunia? stress urinary incontinence and no 10 Yes. 10 Α. overactive bladder onset was found." 11 I think you tried expanding on 11 Do you see that? your answer about the conclusion of the 12 12 study, and I'd like you to take the A. Yes, I do. 13 13 opportunity to finish what you were trying 14 14 And is that generally consistent with your opinions about there being no 15 to say. 15 difference in quality of life improvement 16 16 Eighty-three percent of respondents with de novo dyspareunia would comparing the different prolapse 17 17 18 have had -- would have the procedure done 18 procedures? 19 19 A. Quality of life has been the again. 20 Q. And what does that indicate to 20 same with the -- with the procedures, yes. Q. And the conclusion was: "Mesh 21 you about patient satisfaction or 21 22 subjective cure in this study? exposure occurrence was balanced against a 22 23 MR. BENTLEY: Objection. 23 lower prolapse recurrence rate in patients 24 That indicates to me that 24 undergoing mesh surgery compared with Α. Page 255 Page 257 patient satisfaction was high. 1 those undergoing sacrospinous ligament 1 Looking at table 4, what does 2 2 fixation. that table indicate to you about all the 3 3 Do you see that? 4 different procedures listed there and the 4 A. Yes, that's correct. 5 rates of de novo dyspareunia? 5 If you could just describe how 6 So, in this particular study, 6 you take into account the risk-benefit 7 the rates of de novo dyspareunia after 7 analysis for a more durable repair versus abdominal sacrocolpopexy were 14.5 8 8 the potential complication of mesh 9 percent. Sacrospinous ligament suspension 9 exposure. 36.1 percent. Uterosacral suspension 25.9 10 So, I have a discussion with my 10 11 percent. APR is anterior repair. patient of if we're going to use a 11 Is that anterior and posterior? transvaginal mesh we may get improved 12 12 Q. Anterior and posterior repair 19 durability of the repair. If we use a 13 13 percent. And Prolift at 16.7 percent. transvaginal mesh, understanding that 14 14 Again, although Prolift at 16.7 there is an exposure rate that occurs when 15 15 percent is lower than some of the other 16 16 you use a transvaginal mesh, and some of figures here, you're certainly not those patients may elect to go back to the 17 17 cherry-picking that and suggesting to this operating room for a revision. 18 18 jury that rates of de novo dyspareunia are 19 19 Q. Doctor, the study reports a consistently lower with Prolift compared one-year mesh exposure rate of 20.8 20 20 to native tissue repairs, are you? 21 21 percent. 22 Absolutely not. They're 22 Α. That is correct. Α. 23 23 Of that 20.8 percent, how many equivalent. 24 Doctor, I want to show you 24 of those were symptomatic mesh exposures? Q.

Page 258 Page 260 the type of data plaintiff's experts rely 1 Α. One-quarter of them were 1 2 2 symptomatic. upon. 3 3 O. And what does that mean that --Do you practice medicine based on internal documents? 4 4 what is the difference between symptomatic 5 versus asymptomatic? 5 No, I do not. 6 So, in the symptomatic patients, 6 In residencies and fellowships, 7 the mesh exposure was bothering them, and 7 do they teach based on internal company in the asymptomatic exposures, it was not 8 documents, or is it primarily based on 8 9 evidence-based medicine and the medical bothering them. 9 Doctor, do you see under the 10 10 literature? comments where it states: "However, a 11 11 Α. It's based on the medical significant difference in the recurrence 12 12 literature. rate was found between the groups favoring 13 13 Q. We previously discussed your the mesh group 12 months after surgery"? consulting experience. 14 14 You did, in fact, consult with 15 Α. Yes, I see that. 15 Ethicon on the design of Gynemesh PS? And would you say generally 16 16 A. I discussed with them on design throughout the medical literature, at 17 17 18 least with respect to the anterior 18 of transvaginal mesh. I don't know if compartment, the recurrence rates are they told me it was on Gynemesh PS or not. 19 19 Q. I think you said Prolene Soft 20 significantly lower when a mesh repair is 20 21 undertaken compared to a native tissue 21 mesh and Gynemesh PS are the same mesh? 22 repair? 22 Α. Yes. 23 23 You said you used those from Α. Yes. Q. 24 Q. Do you see in the study where 24 2002 to 2011, approximately? Page 259 Page 261 they showed no significant differences 1 So, I used the Gynemesh PS --1 were observed and changes in quality of are we talking about in my abdominal 2 2 sexual life between sacrospinous fixation sacrocolpopexies are we talking about? 3 3 4 and mesh groups as measured by the PISQ 4 Just in general in your 5 5 short form? practice. 6 6 Α. Yes, I do see that. Α. Yes, somewhere around there. 7 Does that finding surprise you 7 Now, if you would have switched Q. 8 from one product to another, for example 8 at all? 9 9 if you went from Gynemesh PS to a Boston Α. No, it does not. 10 Doctor, you were asked again 10 Scientific Y-mesh, were you doing so about your reliance list, and I think you 11 because of concerns of safety? 11 testified that you reviewed some of No, I was not. When doing it 12 12 plaintiff's expert reports? 13 13 robotically, it's just easier to do it with a Y piece of mesh in my hands as 14 A. Yes. 14 opposed to two separate pieces of mesh. 15 15 And did you also review the 16 documents and studies that they cited in 16 Q. And before you started doing the body of those reports? Prolift, were you already familiar with 17 17 the anatomical landmarks of that 18 A. Yes. 18 19 Q. Doctor, do you practice medicine 19 procedure? 20 Yes, I was. based on --20 A. 21 MR. ROSENBLATT: Well, strike 21 0. How so? 22 22 I already was placing that. transobturator slings. I had already been 23 Doctor, you were asked about 23 24 whether or not you have any criticisms of 24 trained on the Perigee and Apogee meshes.

Page 262 Page 264 1 So I was familiar with the anatomy. 1 practice? 2 Q. I believe you testified that 2 A. Absolutely. 3 your practice has changed somewhat in 3 You were asked some about the terms of you're now offering --4 4 different properties of the meshes and how 5 MR. ROSENBLATT: Well, strike 5 the fiber size is slightly larger with TVT 6 6 compared to Gynemesh PS. that. 7 7 Would you expect the pore sizes O. Doctor, I believe you are 8 implanting less transvaginal mesh now than 8 to be much larger for TVT, which is only 9 you were within the past decade; is that 9 1 centimeter wide? 10 fair? 10 MR. BENTLEY: Objection. 11 A. That's accurate. 11 BY MR. ROSENBLATT: 12 What impact do you think the 12 O. The mesh itself is only 1 Q. litigation and the fear from 13 13 centimeter wide -advertisements has had on your practice? Correct. 14 14 A. MR. BENTLEY: Objection. 15 15 Q. -- for TVT, right? A. So, the -- almost every single So you don't have that much room 16 16 patient that I see and talk to has seen or to make the pores bigger. 17 17 18 heard about the litigation or something 18 In the one patient that you advertised on television, and they -- we described that had bunched mesh, did you 19 19 attribute that to any defect in the mesh? 20 have a discussion about what that 20 21 involves, but I don't think there's any 21 No, I did not. 22 human being in New York that hasn't seen Are all the opinions that you've 22 23 those advertisements. 23 offered here today and in your report held Doctor, the Prolift surgeons to a reasonable degree of medical 24 24 Q. Page 263 Page 265 monograph that you reference in your 1 certainty? 1 report describes a dyspareunia rate of 6 2 2 A. Yes, they are. 3 MR. ROSENBLATT: No further 3 to 9 percent. 4 4 Is that generally consistent questions at this time. 5 with your understanding of the dyspareunia 5 FURTHER EXAMINATION BY 6 rates as reported in 2007? 6 MR. BENTLEY: 7 7 A. Yes, it is. Q. Doctor, your reliance list Doctor, we talked a lot about 8 8 Q. describes the documents reviewed --9 9 reoperation rates. THE WITNESS: Just give me one 10 10 That doesn't necessarily take second. 11 into account failures though, does it, 11 (Discussion held off the record.) prolapse failures? BY MR. BENTLEY: 12 12 Q. Your reliance list, Doctor, 13 A. The reoperation rate includes 13 failures and exposures and everything. lists the documents you reviewed and 14 14 But a patient with a native relied upon to reach your opinions in this 15 15 16 tissue repair may have a failure or 16 case, right? recurrence, but just decides they don't 17 17 A. Yes. want to undergo another procedure for 18 18 And on that list there's a prolapse, so that could be a patient 19 19 number of company documents you reviewed where -- who failed a native tissue 20 and relied upon to reach your opinions 20 repair, but wouldn't undergo another 21 21 here, correct? operation? 22 22 That's correct. Α. 23 That is correct. 23 And you testified that in your Α. 24 And have you seen that in your 24 medical practice, you don't rely upon Q.

Page 266 Page 268 1 company documents, do you? 1 performing prolapse procedures. 2 A. I don't rely on company 2 Specifically limited to that 3 documents to tell me how to do surgery, 3 studv. 4 4 no. Do you remember reading the 5 So it's slightly different here 5 quote that said surgeons were aware of Q. 6 6 in reaching your litigation opinions, you these complications, including dyspareunia 7 did rely upon and review company 7 and pain? 8 8 documents, right? Α. It says: "Pelvic pain and 9 9 MR. ROSENBLATT: Object to form dyspareunia are well-known complications 10 to the extent you're saying he's 10 of the POP procedures." That's great. 11 relied upon. 11 12 A. I may have reviewed them, but I 12 And it doesn't say the frequency did not include the company documents in of transvaginally implanted mesh is 13 13 my medical opinions of the mesh or the well-known, does it? 14 14 Is the word "frequency" in that 15 procedure. 15 16 16 They're on your reliance list sentence? Q. though, right? A. The word "frequency" is not in 17 17 18 They're on the reliance list. 18 Α. the sentence. 19 Doctor, you said you don't rely 19 However, transvaginal mesh is a component of pelvic organ prolapse repair upon a manufacturer to provide you 20 20 21 information about the products; is that 21 surgeries. You can't separate the two 22 22 correct? out. 23 MR. ROSENBLATT: Object to form; 23 Doctor, earlier today we went 24 mischaracterization. 24 through your TVT report, and in your TVT Page 267 Page 269 I don't rely on a manufacturer 1 report, you quoted from ACOG and AUGS, 1 2 2 to give me information regarding -- I didn't you? 3 3 don't rely on manufacturers to tell me how A. Yes, I did. 4 4 But you didn't quote it in your to do surgery. Prolift report, right? 5 5 So in your medical practice, you 6 don't rely upon information provided by 6 A. I didn't use a direct quote. 7 the manufacturers? 7 However, I referenced to that 8 8 A. One of the things that I may report. 9 9 rely on with regarding surgical procedures Q. What was your methodology for that I'm using a device in, yes, I can 10 deciding not to quote the ACOG/AUGS 10 look to see what the company provides, but 11 committee opinion in this report? 11 I may not decide my ultimate decision It didn't give absolute numbers, 12 12 if I remember correctly, on incidences of 13 based solely on what the company provides. 13 So you do rely upon the pain and dyspareunia and one versus the 14 14 information they provide or you don't? 15 15 other. 16 I review it. I don't want to 16 One of the explanations you gave for not citing the other findings in 17 say I solely rely on that. 17 Q. In redirect, counsel asked you Dandolu that were not included in your 18 18 about a study, I think it was the Dandolu, report was you included Dandolu under your 19 19 and it mentioned that surgeons were aware section on page 33 about abdominal mesh 20 20 of the complication dyspareunia and pain; 21 21 and pain; is that correct? 22 is that correct? Do you remember that? 22 MR. BENTLEY: I apologize. Let I think that surgeons should be 23 23 me rephrase that. 24 aware of pain and dyspareunia when they're 24 Q. You include Dandolu on page 33

Page 270 Page 272 under your section for transvaginal mesh 1 1 report. 2 and pain and you didn't provide the other 2 Q. And what is that? 3 finding from Dandolu. 3 It lists the adverse events in 4 the IFU on Prolift. And your explanation for that 4 5 was this was a section just about 5 It also has: "Punctures or 6 transvaginal mesh and pain, right? 6 lacerations of vessels, nerves, bladder, 7 That's correct. 7 urethra or bowel may occur during Gynecare A. 8 But your report, of course, 8 Prolift guide passage and may require 9 discussed the other findings from Dandolu 9 surgical repair." 10 in other sections, right, reoperation rate 10 Q. And my question wasn't what's cited from the IFU in your report. failure, that type of stuff? 11 11 A. I didn't reference Dandolu, but It was what are the common 12 12 we, once again, have -- I admit there is a adverse events that you think are known 13 13 reoperation rate with transvaginal mesh. regarding implantable mesh for the 14 14 treatment of prolapse? 15 Q. Right. 15 It is --16 Exposure, erosion, damage to 16 Α. My question very specifically is other organs, dyspareunia, chronic pelvic 17 17 18 you cited Dandolu under one section, 18 pain, adhesions, scarring. right? You provided one finding from Q. Right. And you think those --19 19 it's your opinion that those have been 20 Dandolu? 20 21 Α. Right. 21 known since -- when were those 22 22 complications known? And your explanation for why you 23 didn't discuss any of the other findings 23 Pain and dyspareunia and all 24 from Dandolu was that Dandolu citation was 24 these -- all the complications except for Page 271 Page 273 in one specific subsection in your report, 1 exposure are commonly associated with 1 2 2 right? pelvic organ prolapse procedures. 3 3 Q. Okay. I believe you included a Α. Right. 4 But my question is the other 4 screen shot from Exhibit 21 in your 5 findings in Dandolu --5 report, and the adverse events from that 6 A. I did cite the Level I evidence 6 marketing piece don't include 7 of reoperation rates in my report. 7 complications such as dyspareunia and Q. But you didn't cite the other 8 8 chronic pain, do they? findings from Dandolu elsewhere in your 9 9 A. Once again, we agreed that it report where you discussed those sections? 10 was not in the IFU of chronic pain and 10 11 A. Dandolu's findings would likely dyspareunia 'cause it was a commonly known 11 be included in the Cochrane review, if it complication which is not required to be 12 12 placed in an IFU, according to CFR 13 was available at that time. 13 Q. Doctor, what are the potential quidelines. 14 14 15 adverse events that are commonly 15 I'm sorry, that wasn't my Q. 16 associated with surgically implantable 16 question. materials such as Gynemesh PS? 17 17 In the exhibit that you're Infection, inflammation, holding in your hand, it lists 18 18 adhesion formation, fistula formation, complications commonly known. 19 19 erosion, extrusion, and scarring that It doesn't include dyspareunia 20 20 results in implant contraction. and chronic pain, does it? 21 21 22 What are you reading from, 22 A. This particular piece of paper Q. 23 Doctor? 23 does not include that. 24 I'm reading from page 17 of my 24 MR. BENTLEY: Thank you. No Α.

	Page 274		Page 276
1	further questions.	1	ERRATA
2	MR. ROSENBLATT: I've got none.	2	PAGE / LINE / CHANGE / REASON
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1	Page 275 ACKNOWLEDGMENT	1	CERTIFICATE
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